1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

TRIPHASIL 50 µg/30 µg; 75 µg/40 µg; 125 µg/30 µg sugar-coated tablets

Ethinyl oestradiol and levonorgestrel

Contains sugar

Brown tablets: Lactose monohydrate 33,070 mg, sucrose 22,526 mg.

White tablets: Lactose monohydrate 33,035 mg, sucrose 19,660 mg

Yellow tablets: Lactose monohydrate 32,995 mg, sucrose 22,481 mg.

Red placebo tablets: Lactose monohydrate 38,006 mg, sucrose 24,599 mg.

Read all of this leaflet carefully before you start taking TRIPHASIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- TRIPHASIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TRIPHASIL is and what it is used for

TRIPHASIL belongs to a group of medicines called combined oral contraceptives (COCs) and is one of a group of medicines often referred to as the Pill. TRIPHASIL contains two types of hormones: an oestrogen, ethinylestradiol, and a progestogen, levonorgestrel. It is a triphasic contraceptive.

This means that there are three levels of hormones in each pack which reflect the changing levels in your normal menstrual cycle. These hormones stop the ovary from releasing an egg each month. They also thicken the mucus at the neck of the womb making it more difficult for the sperm to reach the egg and alter the lining of the womb to make it less likely to accept a fertilised egg.

TRIPHASIL is used to prevent you from becoming pregnant, to control irregularities in the frequency and flow of your menstrual cycle, and to assist with cramps and pain that is normally associated with your menstrual cycle.

Whilst using TRIPHASIL for contraception it may also benefit with acne that may occur.

2. What you need to know before you take TRIPHASIL

Do not take TRIPHASIL:

- if you are hypersensitive (allergic) to ethinyl oestradiol or levonorgestrel or to any of the other ingredients of TRIPHASIL (listed in section 6).
- if you or your close family have ever had problems with blood clotting or if you have the inherited disease called porphyria.
- if you are taking ritonavir (a medicine used to treat HIV infections).

- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs.
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies.
- if you need an operation or if you are off your feet for a long time (see section 'Blood clots').
- if you have ever had a heart attack or stroke.
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms).
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage.
  - high blood pressure.
  - a high level of fat in the blood (cholesterol or triglycerides).
  - a condition known as hyperhomocysteinaemia.
- if you have (or have ever had) a type of migraine called 'migraine with aura'.
- if you have or have ever had breast cancer.
- if you have ever had a severe liver disease, and you have been told by your doctor that your liver function test results are not yet back to normal.
- if you have ever had liver tumours.
- if you become or think you may have become pregnant.
- if you have undiagnosed vaginal bleeding.
- if you have a condition called Dubin-Johnson or Rotor syndromes (condition that

affects the liver).

- if you have depression, which is not well controlled with treatment.
- if you have had depression with previous use of hormonal contraceptives.

Tell your doctor or family planning nurse if you have any medical problems or illnesses.

Warnings and precautions

Take special care with TRIPHASIL:

- if you suffer from severe kidney impairment. You will need to consult with your healthcare professional.
- if you have a history of liver disease or consume large quantities of alcohol.

Seek urgent medical attention if you notice possible signs of a blood clot (see 'Blood clots' section).

This could mean that you are possibly suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism) and a heart attack or stroke.

What to do if you have a stomach upset?

If you have been sick or had diarrhoea, the pill may not work.

Continue to take it, but you may not be protected from the first day of vomiting or diarrhoea.

Use another method, such as a condom, for any intercourse during the stomach upset and for the next seven days.

What to do if you want to delay or to shift your period?

If you want to delay or to shift your period, you should contact your doctor for advice.

General notes

Before you start taking TRIPHASIL you should read the information on blood clots. It is particularly important to read the symptoms of a blood clot (see 'Blood clots' section).

It is important that you understand the benefits and risks of taking TRIPHASIL before you start taking it, or when deciding whether to carry on taking it. Although TRIPHASIL is suitable for most healthy women it isn't suitable for everyone.

Tell your doctor if you have any of the illnesses or risk factors mentioned in this leaflet.

CIGARETTE SMOKING INCREASES THE RISK OF SERIOUS CARDIOVASCULAR SIDE-EFFECTS FROM THE USE OF ORAL CONTRACEPTIVES.THE RISK INCREASES WITH AGE AND WITH HEAVY SMOKING (15 OR MORE CIGARETTES PER DAY) AND IS QUITE MARKED IN WOMEN OVER 35 YEARS OF AGE. YOU ARE THEREFORE ADVISED TO STOP SMOKING IF YOU ARE TAKING TRIPHASIL.

Your doctor will ask about you and your family's medical problems, check your blood pressure and exclude the likelihood of you being pregnant. Tell your doctor or family planning nurse if you have any medical problems or illnesses.

Tell your doctor if any of the following conditions apply to you:

If the condition develops, or gets worse while you are taking TRIPHASIL, you should also tell your doctor.

- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).

- if you have systemic lupus erythematosus (SLE – a disease affecting your natural defence system).
- that you are on treatment for depression.
- that you have had depression with previous use of hormonal contraceptives.
- that you have a substance abuse problem.
- you have underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder.
- that you have a family history of mental disorders.
- that you have a history of physical or sexual abuse.
- if you have haemolytic uraemic syndrome (HUS – a disorder of blood clotting causing failure of the kidneys).
- if you have sickle cell anaemia (an inherited disease of the red blood cells).
- if you have inflammation of the pancreas (pancreatitis).
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas).
- if you need an operation, or you are off your feet for a long time (see Blood clots).
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking TRIPHASIL.
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- if you have varicose veins.
- if you have diabetes.
- if you or your close family have ever had problems with your heart, or circulation such as high blood pressure.

- if you are overweight (obese).
- if you have migraine headaches.
- if you have any illness that worsened during pregnancy or previous use of TRIPHASIL or other oral contraceptives.

Hormonal contraceptives including TRIPHASIL, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behaviour (e.g. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression, that may occur shortly after you start taking TRIPHASIL, contact your doctor for advice.

You may also need other checks, such as a breast examination, but only if these examinations are necessary for you, or if you have any special concerns.

While you're on TRIPHASIL

You will need regular check-ups with your doctor or family planning nurse, usually when you need another prescription of TRIPHASIL.

You should go for regular cervical smear tests.

Check your breasts and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.

If you need a blood test tell your doctor that you are taking TRIPHASIL, because TRIPHASIL can affect the results of some tests.

If you're going to have an operation, make sure your doctor knows about it. You may need to stop taking TRIPHASIL at least 6 weeks before the operation. This is to reduce the risk of a blood clot (see Blood clots). Your doctor will tell you when you can start taking TRIPHASIL again.

Blood clots

Using a combined hormonal contraceptive such as TRIPHASIL increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block vessels and cause serious problems.

Blood clots can develop:

- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE),
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of having a harmful blood clot due to TRIPHASIL is small.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	**What are you possibly suffering from?**
Swelling of one leg or along a vein in the leg or foot especially when accompanied by: • pain or tenderness in the leg which may be felt only when standing or walking • increased warmth in the affected leg • change in colour of the skin on the leg e.g. turning pale, red or blue	Deep vein thrombosis

• sudden unexplained breathlessness or rapid breathing • sudden cough without an obvious cause, which may bring up blood • sharp chest pain which may increase with deep breathing • severe light headedness or dizziness • rapid or irregular heartbeat • severe pain in your stomach If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').	Pulmonary embolism
Symptoms most commonly occur in one eye: • immediate loss of vision or • painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• chest pain, discomfort, pressure, heaviness • sensation of squeezing or fullness in the chest, arm or below the breastbone • fullness, indigestion or choking feeling • upper body discomfort radiating to the back, jaw, throat, arm and stomach • sweating, nausea, vomiting or dizziness • extreme weakness, anxiety, or shortness of breath • rapid or irregular heartbeats	Heart attack

• sudden weakness or numbness of the face, arm or leg, especially on one side of the body • sudden confusion, trouble speaking or understanding • sudden trouble seeing in one or both eyes • sudden trouble walking, dizziness, loss of balance or coordination • sudden, severe or prolonged headache with no known cause • loss of consciousness or fainting with or without seizure Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	Stroke
• swelling and slight blue discolouration of an extremity • severe pain in your stomach (acute abdomen)	Blood clots blocking other blood vessels

See a doctor as soon as possible. Do not take any more TRIPHASIL until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

Blood clots in a vein

What can happen if a blood clot forms in a vein?

- The use of combined oral contraceptives such as TRIPHASIL have been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined oral contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- A clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking TRIPHASIL for the first time. The risk may also be higher if you restart taking TRIPHASIL (the same product or a different product) after a break of 4 weeks or more. After the first year, the risk gets smaller but is always higher than if you were not using TRIPHASIL.

When you stop TRIPHASIL your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk of having a blood clot will vary according to your personal medical history (see Factors that increase your risk of a blood clot in a vein, below).

Factors that increase your risk of a blood clot in a vein

Some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30 kg/m^2).
- if one of your immediate family members has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder.
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of TRIPHASIL may need to be stopped at least 6 weeks before surgery or while you are less mobile. If you need to stop TRIPHASIL ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years).
- if you gave birth recently (approximately 1 month).

The risk of developing a blood clot increases the more conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have

some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that TRIPHASIL needs to be stopped.

If any of the above conditions change while you are taking TRIPHASIL, for example, you start smoking or a close family member experiences a thrombosis for no known reason, or you gain a lot of weight, tell your doctor.

Blood clots in an artery

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery

The risk of a heart attack or stroke from using TRIPHASIL is small but can increase:

- with increasing age (beyond about 35 years).
- if you smoke. When taking a combined hormonal contraceptive like TRIPHASIL, you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive.
- if you are overweight.
- if you have high blood pressure.
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke.
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides).
- if you get migraines, especially migraines with aura.

- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation).
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are taking TRIPHASIL, for example you start smoking, a close family member experiences a thrombosis for no known reason, or you gain a lot of weight, tell your doctor.

TRIPHASIL and cancer

Oral contraceptives, such as TRIPHASIL increase your risk of **cancer of the womb and breast.** All women should have regular **smear tests**.

If you have **breast cancer,** or have had it in the past, you should not take TRIPHASIL. Oral contraceptives, such as TRIPHASIL increase your risk of breast cancer. This risk goes up the longer you're on the Pill but returns to normal within about 10 years of stopping it.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer.
- if you are seriously overweight.

See a doctor as soon as possible if you notice any changes in your breasts, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

TRIPHASIL has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, oral contraceptives have also been linked with some forms of liver cancer in women who have taken them for a long time.

See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (*jaundice*). You may need to stop taking TRIPHASIL.

Other medicines and TRIPHASIL

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- antibiotics (such as ampicillin, tetracycline, and rifampicin).
- medicines used to treat epilepsy or other illnesses, such as primidone, carbamazepine, oxcarbazepine, topiramate, lamotrigine, felbamate, hydantoins or barbiturates (such as phenobarbitone).
- griseofulvin (a medicine used to treat fungal infections).
- certain medicines used to treat depression (tricyclic antidepressants).
- ciclosporin (a suppressor of the immune system used e.g. during transplantation).
- the herbal remedy commonly known as St John's Wort (hypericum perforatum).
- antiviral medicines such as nervirapine or ritonavir, that are used in HIV treatment.

You may have to use another method of contraception as well, such as a condom, while you are taking these medicines and up to 28 days afterwards. Your doctor may advise you to use these extra precautions for even longer.

If you are taking antibiotics, always ask your doctor's advice about extra precautions. Always mention if you are on the combined pill if you are prescribed any medicines.

TRIPHASIL with alcohol

Increasing use of alcohol can affect you when taking TRIPHASIL.

Pregnancy, breastfeeding and fertility

You should not take TRIPHASIL it you are pregnant or think that you may be pregnant or breastfeeding your baby.

TRIPHASIL is contraindicated in confirmed or suspected pregnancy (see section 2 What you need to know before you take TRIPHASIL.) If pregnancy occurs during medication with TRIPHASIL, treatment should be stopped immediately.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

TRIPHASIL is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that TRIPHASIL does not adversely affect your ability to do so safely (see section 4).

TRIPHASIL contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking TRIPHASIL.

3. How to take TRIPHASIL

Do not share medicines prescribed for you with any other person.

Always take TRIPHASIL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This pack is designed to help you remember to take your pills.

Starting the first pack

Take the first pill on the first day of your period. This is day one of your cycle - the day when bleeding starts.

If you start taking the pill on day 2 to 5 of your period, you should use another method of contraception as well, such as the condom, for the first seven pill-taking days, but this is only for the first pack.

You can take your pill at any time, but you should take it about the same time each day. You may find it easiest to take it either last thing at night or first thing in the morning. Take a pill every day in the order shown until you finish all 21 active pills in the pack.

Once you have taken all 21 active pills, there will be seven pill-free (placebo) days. You will probably start bleeding after about 2 to 3 days and for several of those 7 days.

You do not need to use any other form of contraception during the seven-day break provided you have taken the 21 pills properly and you start the next pack on time. However, if you are unsure please consult with your healthcare provider on alternative method of contraception such as a condom to be used together with TRIPHASIL.

The next pack

After seven pill-free (placebo) days, start your next pack. Do this whether or not you are still bleeding. You will always start a new pack on the same day of the week.

Changing to TRIPHASIL from another combined hormonal contraceptive (combined pill, vaginal ring, transdermal patch)

You should start with TRIPHASIL on the day after you took the last active pill in your previous

blister pack of contraceptive pills (or removed the transdermal patch or vaginal ring). The next pack should be started no later than on the day after the usual pill-free (or placebo, patch-free or ring-free) interval with your previous contraceptive.

Changing to TRIPHASIL from a progestogen-only pill

You can stop taking the pills that only contain progestogen any time and start taking TRIPHASIL the next day at the same time point. But be sure to use additional contraceptive precautions (such as condoms or spermicides) during intercourse in the first 7 days, during which you take the pills.

Changing to TRIPHASIL from a contraceptive injection or implant

If you have had an injection or implant of a progestogen hormone, you can start to take TRIPHASIL on the day that your next injection is due, or on the day that your implant is removed. However, you should use another method of contraception (such as condoms or spermicides) during intercourse in the first 7 days, during which you take the pills.

Starting after childbirth or miscarriage or abortion

After a birth, abortion or miscarriage, your doctor should advise you about taking the pill.
You can start taking TRIPHASIL immediately after a miscarriage or abortion which occurs during the first three months of pregnancy. In this case it is not necessary to take further contraceptive measures.
If you have had a delivery or abortion which occurs during the second trimester of pregnancy, you can start taking TRIPHASIL 21 to 28 days after giving birth or having an abortion. If you start later, an alternative contraception (such as the condom) must be used for the first 7 days of pill-taking. If you have had unprotected sex, you should not start TRIPHASIL until your period starts or you are sure you are not pregnant.

If you are breastfeeding, the combined pill is not recommended because it can reduce your flow of milk. If you have any questions about starting TRIPHASIL after childbirth or abortion, ask your doctor or pharmacist.

If you forget to take / miss a dose of TRIPHASIL

If you forget to take a pill please follow these instructions.

If one pill is 12 hours late or less

Your contraceptive protection should not be affected if you take the late pill at once and keep taking your next pill at the usual time. This may mean taking two pills in one day.

If you are more than 12 hours late in taking a pill, or have missed more than one pill

If you are more than 12 hours late in taking a pill, or you have missed more than one pill, your contraceptive protection may be lower so you must use extra protection. The more pills you have missed, the more risk there is that your contraceptive protection is reduced. In this case follow the instructions for daily practice:

What to do if you miss a pill during the first week?

You must take the last missed pill as soon as you remember, even if this means that you have to take 2 pills at the same time.

Thereafter, you should continue taking the pills at the usual time of the day. You must also use a barrier method of contraception, e.g. a condom, for the next 7 days. If intercourse has taken place during the preceding 7 days the possibility of pregnancy must be considered.

The more missed pills and the closer to the 7 pill-free (placebo) interval this happens, the

greater the risk of pregnancy.

What to do if you miss a pill during the second week?

You must take the last missed pill as soon as you remember even if this means that you have to take 2 pills at the same time.

Thereafter, you should continue taking the pills at the usual time of the day.

Provided that the pills have been taken in a correct manner during the 7 days preceding the missed pill, it is not necessary to take further contraceptive measures. However, if this is not the case,

or if more than 1 pill has been missed, you should use another contraceptive method for 7 days.

What to do if you miss a pill during the third week?

You should take the last missed pill as soon as you remember, even if it means that you have to take 2 pills at the same time. Thereafter, you should continue taking the pills at the usual time of the day.

You should then start the next pack immediately after taking the last active pill in the current pack, i.e. without a 7 day pill-free (placebo) interval between the packs. Withdrawal bleeding is unlikely until the end of the second pack, but there may be some spotting, or break-through bleeding, on the days you are taking pills.

Alternatively, you may also stop taking pills from the current pack. In that case, you should keep a period without pills of up to 7 days, including those days when you forgot to take your pills, and thereafter continue with the next pack.

If you have missed pills and then do not get a withdrawal bleed in the first normal 7day pill-

free (placebo) interval, the possibility of pregnancy must be considered.

If you take more TRIPHASIL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you take more TRIPHASIL than you should, it is not likely that it will do you any harm, but you may feel sick, actually be sick or have some vaginal bleeding. If you have any of these symptoms, you should talk to your doctor who can tell you what, if anything, you need to do.

4. Possible side effects

TRIPHASIL can have side effects.

Not all side effects reported for TRIPHASIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRIPHASIL, please consult your healthcare provider for advice.

If any of the following happens, stop taking TRIPHASIL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to TRIPHASIL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Also, do not take any more pills until you have spoken to your doctor. In the meantime, use another method of contraception such as a condom or cap plus spermicide.

- if you get a migraine for the first time or if you already have migraines but they get

worse or happen more often than before,

- breast cancer (symptoms may include, a lump or mass, discharge from your nipple, breast rash, pain in your breast),
- liver tumour (benign or malignant, symptoms may include loss of appetite, stomach pain, vomiting, weakness),
- you develop symptoms of a blood-clot formation,
- a sudden loss of brain function caused by a blockage or rupture of a blood vessel to the brain (loss of muscular control),
- heart attack,

These symptoms include:

- unusual pain or swelling in your legs,
- sudden sharp pains in your chest which may reach your left arm,
- sudden shortness of breath or difficulty in breathing,
- sudden coughing for no apparent reason,
- any unusual, severe or long-lasting headache,
- any sudden changes to your eyesight (such as loss of vision or blurred vision),
- slurred speech or any other difficulties affecting your speech,
- vertigo (spinning sensation),
- dizziness, fainting or fits,
- sudden weakness or numbness in one side or part of your body,
- difficulties in moving around (known as motor disturbances,) or severe pain in your abdomen (known as acute abdomen),
- you require surgery or become immobilised (not being able to move around as normal), since this may increase the risk of blood clot formation. You should stop taking TRIPHASIL at least four weeks before a planned major operation (for example,

stomach surgery), or if you are having any surgery to your legs. Also, if you are immobilised for a long time (for example, you are in bed after an accident or, operation, or you have a plaster cast on a broken leg). Your doctor will tell you when you can start taking TRIPHASIL again,

- suicidal thoughts/ behaviour and suicide attempts,
- Crohn's disease, where your digestive tract becomes swollen, irritated and painful and can lead to severe diarrhoea, fatigue, weight loss and malnutrition that can be life threatening,
- cholestatic jaundice, obstruction of bile flow. Symptoms include jaundice, which is a yellowing of your skin and the white of your eyes, intense itching, dark urine and light-coloured bowel movements,
- inflammation of the pancreas (with the major symptoms: severe pain in the abdomen, nausea, fever),
- a disease of the connective tissue, called systemic lupus erythematosus (SLE).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Tender breasts, breast gets bigger or something secreted from it,
- depressive moods,
- headaches,
- feeling sick (nausea),
- gall stone disease,
- skin disorders such as acne,
- brown patches on the face and body like those that occur in pregnancy,
- irregular bleeding or missed bleeds,

- bleeding or spotting between your periods,
- excess water collecting in the body,
- increase or decrease in body weight,
- tummy pain.

Less frequent side effects:

- Changes in interest in sex,
- nervousness,
- high blood pressure,
- presence of excess lipids in the blood called hyperlipidaemia,
- changes in appetite,
- impaired hearing (otosclerosis),
- stomach cramps, bloatedness, being sick, bloody diarrhoea (ulcerative colitis)
- hair loss, loss of scalp hair,
- inflammation of the bladder,
- diminution or loss of sensation or consciousness,
- dizziness, slurred speech,
- a movement disorder called Sydenham's chorea,
- visual disturbance (such as temporal loss of vision, blurred vision or double vision),
- intolerance to contact lenses,
- exacerbation of hereditary angioedema,
- fluid retention,
- exacerbation of chorea (movement disorder),

- skin pigmentation,
- breast hypertrophy,
- vaginal discharge,
- breast secretion,
- post pill amenorrhoea,
- vaginal candidiasis,
- vaginitis,
- precipitation of acute attack of porphyria,
- haemolytic uremic syndrome,
- haemorrhagic eruption.

Side effects with an unknown frequency:

- Hirsutism, excessive hair growth anywhere on the body in either males or females,
- cystitis like syndrome (chronic condition causing bladder pressure, bladder pain and sometimes pelvic pain),
- cervical erosion or secretion,
- inflammation of walls of veins that can cause pain, swelling and tenderness,
- sensation of heaviness,
- an abnormal absence or infrequent menstrual periods, skipping of a women's cycle, breast disorders, oligomenorrhoea.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA:https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of TRIPHASIL.

5. How to store TRIPHASIL

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

TRIPHASIL contains six (6) brown active sugar-coated tablets, five (5) white active sugar-coated tablets, ten (10) yellow active sugar-coated tablets and seven (7) red placebo sugar-coated tablets.

The active substances are levonorgestrel and ethinyl estradiol.

Active tablets:

Each brown active sugar-coated tablet of TRIPHASIL contains 50 µg of levonorgestrel and 30 µg of ethinyl estradiol.

The other ingredients are: Calcium carbonate light, iron oxide red (C.I. 77492), iron oxide yellow (C.I. 77491), lactose monohydrate, magnesium stearate, methyl paraben, polyethylene glycol, povidone, propyl paraben, sucrose, starch maize, talc purified, titanium dioxide (C.I. No: 77891), Waradur XE.

Preservatives:

Methyl paraben 0,001 % *m/m*

Propyl paraben 0,001 % *m/m*

Contains sugar: Lactose monohydrate 33,070 mg and sucrose 22,526 mg.

Each white active sugar-coated tablet of TRIPHASIL contains 75 µg of levonorgestrel and 40 µg of ethinyl estradiol.

The other ingredients are: Calcium carbonate light, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, sucrose, starch maize, talc purified, Waradur XE.

Contains sugar: Lactose monohydrate 33,035 mg, sucrose 19,660 mg.

Each yellow active sugar-coated tablet of TRIPHASIL contains 125 µg of levonorgestrel and 30 µg of ethinyl estradiol.

The other ingredients are: Calcium carbonate light, iron oxide red (C.I. 77492), iron oxide yellow (C.I. 77491), lactose monohydrate, magnesium stearate, methyl paraben, polyethylene glycol, povidone, propyl paraben, sucrose, starch maize, talc purified, titanium dioxide (C.I. No: 77891), Waradur XE.

Preservatives:

Methyl paraben 0,001 % m/m

Propyl paraben 0,001 % m/m

Contains sugar: Lactose monohydrate 32,995 mg and sucrose 22,481 mg.

Each red placebo sugar-coated tablet of TRIPHASIL contains sugar: Lactose monohydrate 38,006 mg, sucrose 24,599 mg.

The other ingredients are: Calcium carbonate light, FD&C Red No. 3 Lake (C. I. 45430), FD&C Yellow 6 (C.I. 15985), lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, Ponceau 4R Aluminium Lake (C. I. 16255), povidone, sodium benzoate, sucrose, talc purified, Quinoline Yellow Aluminium Lake (C.I. 47005), Waradur XE.

Preservative:

Sodium benzoate 0,002 % *m/m*

What TRIPHASIL looks like and contents of the pack

Brown active sugar-coated tablet: Pale brown, lustrous, round biconvex sugar-coated tablet.

White active sugar-coated tablet: White, lustrous, round biconvex sugar-coated tablet.

Yellow active sugar-coated tablet: Yellow, lustrous, round biconvex sugar-coated tablet.

Red placebo sugar-coated tablet: Red biconvex sugar-coated tablet.

28 sugar-coated tablets comprising of six (6) brown active, five (5) white active, ten (10) yellow active and seven (7) red placebo pills are packed in a clear polyvinylchloride blister strip, sealed with an aluminium foil backing. The blister strip is packed in an outer cardboard carton together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Registration number

N/18.8/0040

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: B9320080 S2

Namibia: NS2 90/18.8/001250

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