SCHEDULING STATUS:

S4

MYTRICON 150 mg/ml

Suspension for injection

Medroxyprogesterone acetate

Sugar free

Read all of this leaflet carefully before you are given MYTRICON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What MYTRICON is and what it is used for

MYTRICON contains the active substance medroxyprogesterone acetate. Medroxyprogesterone acetate acts by preventing an egg from fully developing and being released from the ovaries during your menstrual cycle. If an egg is not released it cannot become fertilised by sperm and result in pregnancy. Medroxyprogesterone acetate also causes changes in the lining of your womb that

makes it less likely for pregnancy to occur. It also thickens the mucus at the entrance of the womb, making it more difficult for sperm to enter. The anti-cancer activity of medroxyprogesterone acetate at high doses is not fully understood.

MYTRICON is used for:

1. Endometriosis (a condition resulting from the appearance of endometrial tissue outside the uterus and causing pelvic pain, especially associated with menstruation).
2. Contraception (ovulation suppression): long-term female contraception every 3 months.
3. Endometrial Cancer: as add-on and/or to improve treatment.
4. Kidney Cancer: as add-on and/or to improve treatment.

2. What you need to know before you are given MYTRICON

MYTRICON should not be administered to you:

- if you are hypersensitive (allergic) to medroxyprogesterone acetate or any of the other ingredients of MYTRICON (listed in section 6).
- if you are or think you may be pregnant.
- if you have known or suspected breast cancer.
- if you have unexplained vaginal bleeding.
- if you have unexplained blood in your urine.
- if you have unexplained abnormalities with your breast(s).
- if you have liver problems.
- if you have or previously had inflammation of the veins (thrombophlebitis).
- if you have depression which is not well controlled with treatment.
- if you have had depression with previous use of hormonal contraception.

Warnings and precautions

Your doctor will ask about you and your family's medical problems, check your blood pressure and exclude the likelihood of you being pregnant. 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.

Tell your doctor or other health care provider before being given MYTRICON:

- if you have risk factors for osteoporosis including bone disease, excessive alcohol and/or tobacco use, a low body mass index (BMI) or eating disorder (e.g., anorexia or bulimia), strong family history of osteoporosis or chronic use of medicines that can reduce bone mass density such as anti-epileptics (used for seizures) or steroids.
- if you have diabetes or a family history of diabetes.
- if you have severe pain or swelling in the calf (indicating a possible clot in the leg, which may be called phlebitis).
- if you have blood clotting disorders such as deep vein thrombosis (blood clot in the legs), pulmonary embolus (blood clot in the lung) or a stroke you should not receive further injections of MYTRICON.
- if you have problems with your eyesight while using MYTRICON, for example a sudden partial or complete loss of vision or double vision.
- if you have a history of abnormal or unexpected vaginal bleeding as you may need additional examination or testing before using MYTRICON.
- if you have a past history of or current depression.
- if you have had depression with previous use of hormonal contraceptives.
- if you have problems with your liver or liver disease.
- if you have problems with your kidneys or kidney disease.

- if you have a history of heart disease or cholesterol problems including any family history.
- if you have a condition that may be affected by weight gain or fluid retention as MYTRICON may cause these conditions to worsen (e.g., epilepsy, migraine, asthma or problems with your heart or kidneys).
- if you are using certain medicines such as high dose glucocorticoids (steroids), anti-epileptics, and thyroid hormones. Tell the person who provides your contraception if you are taking these or any other medicines - they may recommend a more suitable method of contraception.

Psychiatric disorders

Some women using hormonal contraceptives including MYTRICON have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Possible effect on your periods

MYTRICON will usually disturb the pattern of a woman’s period. After the first injection it is most likely that you will have irregular, possibly lengthy bleeding or spotting. This will continue in some women. This is quite normal and nothing to worry about. One third of women will not have any bleeding at all after the first injection. After 4 injections, most women find that their periods have stopped completely. Not having periods is nothing to worry about. If you experience very heavy or prolonged bleeding, you should talk to your doctor. This happens rarely but can be treated. When you stop receiving MYTRICON your periods will return to normal in a few months.

Possible effects on your bones

MYTRICON works by lowering levels of oestrogen and other hormones. However, lower oestrogen levels can cause bones to become thinner (by reducing bone mineral density). Women who use MYTRICON tend to have lower bone mineral density than women of the same age who have never used it. The effects of MYTRICON are greatest in the first 2-3 years of use. Following this, bone mineral density tends to stabilise and there appears to be some recovery of bone density when MYTRICON is stopped. It is not yet possible to say whether MYTRICON increases the risk of osteoporosis (weak bones) and fractures in later life (after the menopause).

The following are risk factors in the development of osteoporosis in later life. You should discuss with your doctor before starting treatment if you have any of the following as an alternative contraceptive may be more suitable to your needs:

- chronic alcohol and/or tobacco use;
- chronic use of medicines that can reduce bone mass, e.g. epilepsy medication or steroids;
- low body mass index or eating disorder, e.g. anorexia nervosa or bulimia;
- previous low trauma fracture that was not caused by a fall;
- strong family history of osteoporosis.

Teenagers (up to 18 years)

Normally, the bones of teenagers are rapidly growing and increasing in strength. The stronger the bones are when adulthood is reached, the greater the protection against osteoporosis in later life. Since MYTRICON may cause teenage bones to become thinner at a time when they should be growing, its effect may be particularly important in this age group. Bones start to recover when MYTRICON is stopped, but it is not yet known whether the bone mineral density reaches the

same levels as it would have if MYTRICON had never been used. You should therefore discuss whether another form of contraception might be more suitable for you with the person who provides your contraception before starting MYTRICON.

If you use MYTRICON, it may help your bones if you take regular weight-bearing exercise and have a healthy diet, including an adequate intake of calcium (e.g. in dairy products) and vitamin D (e.g. in oily fish).

Possible risk of cancer

Studies of women who have used different forms of contraception found that women who used MYTRICON for contraception had no increase in overall risk of developing cancer of the ovary, womb, cervix or liver.

Possible risk of breast cancer

Breast cancer is rare among women under 40 years of age whether or not they use hormonal contraceptives. MYTRICON may increase the risk of breast cancer slightly compared with women who have never used it. However, any excess risk is small in relation to the overall risk of breast cancer, particularly in young women. Older women have a higher baseline risk of breast cancer and therefore the increase in the number of cases due to MYTRICON is greater in older women than in younger women.

Possible risk of forming an abscess at the injection site

As with any intramuscular injection, there is a risk of an abscess forming at the site of injection. This may require medical or surgical attention.

Possible risk of weight gain

Some women gained weight while using MYTRICON. Studies show that over the first 1-2 years of use, the average weight gain was 5 - 8 lbs (2,6 kg). Women completing 4-6 years of therapy gained an average of 14 - 16,5 lbs (6 – 7,48 kg).

Cervical smear testing

The results of a cervical smear and some laboratory tests could also be affected if you are using MYTRICON so it is important that you tell your doctor.

Protection against sexually transmitted infections

MYTRICON does not protect against HIV infection, e.g. AIDS and other sexually transmitted infections. Safer sex practices, including correct and consistent use of condoms, reduce the transmission of sexually transmitted infections through sexual contact, including HIV.

Other medicines and MYTRICON

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or healthcare professional if you are taking a medicine called aminoglutethiamide (medicine used to treat Cushing's syndrome and certain breast and prostate cancers) or other medicines that thin your blood (anticoagulants) as these may affect the way MYTRICON works.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before being given MYTRICON.

Pregnancy:

Your doctor will check that you are not pregnant before giving you the first injection and also if any following injection is delayed beyond 89 days (12 weeks and 5 days). MYTRICON is not recommended if you are pregnant as hormonal medicines can affect the developing baby.

Effect on future fertility:

Your usual level of fertility should return when the effect of the injection has worn off. This takes different amounts of time in different women and does not depend on how long you have been using MYTRICON.

If you are breastfeeding:

MYTRICON does not prevent the breast from producing milk so nursing mothers can use it; however, it is better for the baby that for the first few weeks after birth its mother's milk contains no traces of any medicines, including MYTRICON. Your doctor or healthcare professional may advise that you wait until at least 6 weeks after your baby has been born before you start using MYTRICON for contraception. If a baby is exposed to MYTRICON in the breast milk, no harmful effects have been seen in babies and children.

Driving and using machines

MYTRICON may cause headaches and dizziness. Therefore, be careful until you know whether this medicine affects your ability to drive or use machines. If you have any concerns discuss them with your doctor.

3. How to use MYTRICON

MYTRICON is an intramuscular injection (injected into the muscle) and will be administered by your doctor, nurse or other health care provider. MYTRICON should be shaken well immediately before use.

Endometriosis:

The usual dose of MYTRICON in this condition is 50 mg weekly or 100 mg every 2 weeks intramuscularly for at least 6 months.

Contraception:

MYTRICON will be given to you every 12 weeks as a single intramuscular injection of 1 ml (150 mg medroxyprogesterone acetate) into the buttock or upper arm. The injection is given during the first 5 days after the beginning of a normal menstrual period. Following childbirth, the first MYTRICON injection can be given within 5 days after childbirth if you are not breastfeeding, or, if exclusively breastfeeding, at or after the sixth week after giving birth to reduce risk that you are pregnant.

MYTRICON works as a contraceptive for 12 weeks in your body. There is no way of reversing the injection once it is given. For effective contraceptive cover, MYTRICON must be given every 12 weeks. Make sure that you or your doctor makes your next appointment for 12 weeks' time.

If the time period since your last injection is more than 14 weeks, your health care provider will need to confirm that you are not pregnant before you are given another injection.

Consult with your health care provider when switching from other methods of birth control (e.g., oral contraceptive pill) to ensure correct timing of the first MYTRICON injection to provide continuous birth

control coverage.

Endometrial and renal carcinoma:

Doses of 400 mg to 1000 mg of MYTRICON intramuscularly per week are recommended initially. If improvement is noted within a few weeks or months and the disease appears stabilised, it may be possible to maintain improvement with as little as 400 mg per month.

Use in children:

MYTRICON is not indicated if you have not yet started your periods.

If you receive more MYTRICON than you should

Since a health care provider will administer MYTRICON, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget an injection of MYTRICON

If you forget your injection or are late getting your next injection (i.e. wait longer than 12 weeks between injections), there is a greater risk that you could become pregnant. Ask your doctor or healthcare professional to find out when you should receive your next injection of MYTRICON and which type of contraception should be used in the meantime.

4. Possible side effects

MYTRICON can have side effects.

Not all side effects reported for MYTRICON are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving MYTRICON, please consult your health care provider for advice.

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

- sudden skin rash or itching (especially affecting the whole body), swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to MYTRICON. 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:

Less frequent:

- a blood clot in the lungs (symptoms include shortness of breath, breath-related chest pains, coughing up blood);
- a blood clot in the leg (you may have pain, tenderness or swelling in your calf, ankle or foot or you may have painful or inflamed veins in your leg; you may find it difficult to put full weight on the affected leg or you have purple discolouration of the skin of the leg or the skin becomes red and warm to touch);
- jaundice (yellowing of the skin or the whites of the eyes).

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

Tell your doctor if you notice any of the following:

When used for contraception:

Frequent

- nervousness,
- headache,
- dizziness,
- stomach pain or discomfort,
- weight increase or decrease,
- depression,
- libido decreased (reduced sex drive),
- feeling sick,
- feeling bloated,
- hair loss,
- acne,
- back pain,
- vaginal discharge,
- breast tenderness,
- difficult or painful period,
- urinary tract infection,
- oedema/fluid retention,
- weakness.

Less frequent

- appetite increased or decreased,
- difficulty sleeping,
- convulsions (fits),
- drowsiness,
- tingling,

- hot flush,
- liver disorder,
- facial hair growth,
- nettle rash or hives,
- itchy skin,
- temporary brown patches,
- difficult or painful period,
- unexpected or unusual vaginal bleeding or spotting,
- milky discharge from the breast when not pregnant or breastfeeding,
- pelvic pain,
- painful intercourse,
- prevention of lactation,
- breast cancer,
- reduction in red blood cell,
- blood disorder,
- difficulty reaching orgasm,
- behavior change,
- mood change,
- irritability,
- anxiety,
- migraine,
- paralysis,
- fainting,
- feeling of dizziness or spinning,
- heart beats more rapidly,
- high blood pressure,

- varicose veins,
- diarrhoea,
- rectal bleeding,
- digestive disorder,
- liver enzyme disorder,
- accumulation of fat (at injection site),
- inflammation of the skin,
- scar tissue formation,
- stretch marks,
- pain in a joint,
- muscular cramps,
- bone density decreased,
- osteoporosis (decrease in bone strength) including osteoporotic fractures,
- vaginal pain or inflammation,
- stopping or extended break of your periods,
- breast pain,
- uterine bleeding or excessive bleeding,
- periods with abnormally heavy or prolonged bleeding,
- vaginal dryness,
- change in breast size,
- ovarian or vaginal cyst,
- premenstrual syndrome,
- excessive thickening of the lining of the womb,
- breast lump,
- nipple bleeding,
- delayed egg release with longer menstrual cycles (periods),

- feel pregnant,
- abnormal smear,
- fever,
- tiredness,
- injection site pain or tenderness,
- injection site lump or dimple,
- feeling thirsty,
- hoarseness,
- facial nerve paralysis,
- decreased sugar tolerance.

Frequency not known

- severe depression with a higher risk of suicidal thoughts/behaviour and suicide.

When used for cancer:

Frequent side effects

- increased weight,
- tremors,
- increased sweating,
- swelling of feet and ankles,
- fluid retention.

Less frequent side effects

- rounded appearance of the face (‘moon-face’),
- inflammation of the veins,
- irregular and/or increased/decreased menstrual bleeding or spotting,

- fever.

Frequency not known

- osteoporosis (decrease in bone strength) including osteoporotic fractures,
- abnormal liver function test,
- severe depression with a higher risk of suicidal thoughts/behaviour and suicide,
- loss of fat tissue,
- injection site reactions including pain or tenderness at site of injection, persistent indentation or dimpling,
- lump or nodule at site of injection.

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 via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MYTRICON.

5. How to store MYTRICON

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Do not freeze.
- Do not use after the expiry date stated on the carton or label.

6. Contents of the pack and other information

What MYTRICON contains

- The active substance is medroxyprogesterone acetate.

  Each ml contains 150 mg medroxyprogesterone acetate.

  Preservatives: methylparaben 0,137 %, propylparaben 0,015 %.

  Sugar free.
- The other ingredients are methylparaben (E218), polyethylene glycol 3350, polysorbate 80, propylparaben (E216), sodium chloride, water for injection.

What MYTRICON looks like and contents of the pack

MYTRICON is a white to off-white suspension.

MYTRICON is available as 1 ml of suspension filled in a 2 ml clear, type I, glass vial sealed with a grey, bromobutyl rubber stopper and white, flip-off, aluminium seal. Packs of 1 or 25 single dose vials per carton.

Holder of Certificate of Registration

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