1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S6

CYCLIMORPH 10 injection (10 mg/50 mg per 1 ml)

CYCLIMORPH 15 injection (15 mg/50 mg per 1 ml)

Morphine tartrate and cyclizine tartrate

Read all of this leaflet carefully before CYCLIMORPH is administered to you

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

What is in this leaflet

1. What CYCLIMORPH is and what it is used for

CYCLIMORPH contains the active ingredients morphine tartrate and cyclizine tartrate.

Morphine tartrate belongs to a group of medicines called opioid analgesics and is used for pain relief.

Cyclizine belongs to a group of medicines called anti-emetics which reduce any nausea and vomiting that may occur.

CYCLIMORPH is used to relieve moderate to severe pain and nausea in certain medical or surgical situations.

2. What you need to know before CYCLIMORPH is administered to you

CYCLIMORPH should not be administered to you:

- if you are hypersensitive (allergic) to morphine tartrate or cyclizine tartrate or any of the other ingredients of CYCLIMORPH (listed in section 6).
- if you have respiratory depression, especially in the presence of cyanosis (low oxygen levels) and excessive bronchial secretions.
- if you have bronchial asthma, or in heart failure secondary to chronic heart disease.
- if you have acute alcoholism, head injury and raised intracranial pressure.
- if you have acute alcohol intoxication.
- if you are receiving monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- if you have ulcerative colitis since it may precipitate toxic dilation or spasm of the colon.
- if you have severe kidney impairment.
- if you have severe liver impairment.
- if you are at risk of paralytic ileus (a condition where there is inactivity or paralysis within the bowel which stops the passage of material within the intestine) or delayed gastric emptying (a condition that effects the stomach muscles and prevents proper stomach emptying).
- if you have a spasm in the bile duct or kidney duct or if you have recently had an operation in the bile duct.

- if you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with CYCLIMORPH:

- if you are very young, elderly, very ill or debilitated.
- if you have an underactive thyroid, adrenocortical insufficiency, deficiency in pituitary hormone, or a neuromuscular disorder.
- if you have glaucoma.
- if you have an inflammatory or obstructive disease of the gastrointestinal tract.
- if you have severe heart failure.
- if you are alcohol dependant.
- if you have previously suffered from alcohol or drug withdrawal symptoms (such as shaking, confusion, high blood pressure, hallucinations).
- if you have low blood pressure as it may lower your blood pressure even further.
- if you have porphyria.
- if you have diabetes.
- if you are a man with an enlarged prostate gland.
- if you are suffering from shock.
- if you are currently suffering from pancreatitis.
- if you are suffering from abdominal pain or lower back pain.
- if you suffer from an immune disorder characterised by muscle weakness (myasthenia gravis).
- if you have a history of drug dependence i.e. you have been reliant on particular medicines.
- if you suffer from fits (convulsions).

- if you experience wheezing, trouble breathing, tiredness, swelling of the lower limbs (these are symptoms of cor pulmonale caused by chronic lung disease).
- if you have a condition in which the liquid portion of the blood (plasma) is too low (known as hypovolaemia).
- if you have a disorder that occurs when your body does not produce enough of certain hormones (known as adrenal insufficiency). Symptoms of adrenal insufficiency may include nausea, vomiting, loss of appetite, fatigue, weakness, dizziness, or low blood pressure.
- if you suffer from a tumour of the adrenal gland with symptoms such as high blood pressure, sweating, rapid heartbeat and headache (known as phaeochromocytoma).
- if you suffer from acute chest syndrome (chest pain, cough, fever, low oxygen level) caused by sickle cell disease (a blood disorder).
- if you suffer from an increased sensitivity to feeling pain and an extreme response to pain (known as hyperalgesia).
- if higher doses of CYCLIMORPH are administered and you experience an unrealistic feeling of well-being (known as euphoria).
- if CYCLIMORPH is administered long-term and you experience a decrease in sexual desire, a loss of sexual ability (if you are male) and if you are female, you experience the absence of menstrual periods.
- if you feel that you need to be given more of CYCLIMORPH to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it.
- if you experience withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor will discuss with you how your dose will be gradually reduced

before stopping the medicine. It is important that you should not stop being administered CYCLIMORPH suddenly as you will be more likely to experience withdrawal symptoms.

Children and adolescents

CYCLIMORPH injection should not be used in children under 12 years of age.

Other medicines and CYCLIMORPH

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:

- Monoamine oxidase inhibitors (MAOI), a medicine used to treat depression.
- Rifampicin, an antibiotic, used in the treatment of tuberculosis.
- Phenytoin, an anticonvulsant, used to treat epilepsy.
- St John's Wort, used for depression.
- Alcohol.
- Barbiturates or neuromuscular blocking medicines used in surgery e.g. phenobarbitone.
- Tranquilisers or benzodiazepines e.g. diazepam.
- Psychotropic medicines such as phenothiazines used to treat mental disorders.
- Medicines for irregular heartbeats (e.g. mexiletine).
- Medicines for heart problems including propranolol, or esmolol; or for high blood pressure including diuretics (water tablets).
- Cimetidine, used to treat ulcers.
- Dexamphetamine, used to treat attention deficit hyperactivity disorder (ADHD).

- Central nervous system (CNS) depressants, used to treat anxiety, tension, and sleep disorders, as well as alcohol.
- Atropine an anticholinergic medicine, used during surgical procedures.
- Tricyclic antidepressants, used to treat depression.
- Antihistamines such as hydroxyzine.
- Oral P2Y12 inhibitor antiplatelets such as aspirin.
- Ritonavir used along with other medicines to treat HIV.

CYCLIMORPH with food, drink and alcohol

Do not drink alcohol while being treated with CYCLIMORPH, as the injection can increase the effects of alcohol.

Alcohol can also enhance the CNS depressant effect of CYCLIMORPH.

Pregnancy, breastfeeding and fertility

You should not take CYCLIMORPH if you are pregnant or breastfeeding your baby (see section 2).

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 receiving this medicine.

CYCLIMORPH may reduce fertility.

Driving and using machines

CYCLIMORPH has major influence on the ability to drive and use machines.

Patients experiencing hypotension, drowsiness or sedation while receiving CYCLIMORPH, should refrain from driving or using machines.

It is not always possible to predict to what extent CYCLIMORPH may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which CYCLIMORPH affects you (see section 4).

CYCLIMORPH contains sodium metabisulphite

Sodium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How CYCLIMORPH will be administered to you

CYCLIMORPH is administered subcutaneously, intramuscularly or intravenously.

The usual adult dose is 1 ampoule of CYCLIMORPH 10 or CYCLIMORPH 15.

If required, CYCLIMORPH can be administered no more often than 4 hourly. You should not be administered more than 3 doses in any 24-hour period.

Your doctor will tell you how long your treatment with CYCLIMORPH will last. Do not stop treatment early. If you have the impression that the effect of CYCLIMORPH is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself CYCLIMORPH. CYCLIMORPH will be administered to you by a person who is qualified to do so.

Use in the elderly:

If you are an elderly patient your doctor will reduce the dose.

If you are administered more CYCLIMORPH than you should

Since a healthcare professional will administer CYCLIMORPH, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive CYCLIMORPH

Since a healthcare provider will administer CYCLIMORPH, it is unlikely that the dose will be missed.

If you stop receiving CYCLIMORPH

Some people may become addicted to CYCLIMORPH when treatment continues for a long time.

Some people may experience drug withdrawal symptoms after stopping treatment with CYCLIMORPH. If any of the side effects becomes severe, or if you notice any side effect not listed in this leaflet, please tell your doctor.

If you no longer require CYCLIMORPH, your doctor will taper the dose gradually to minimise symptoms of withdrawal. Tapering from a high dose may take weeks to months.

4. Possible side effects

CYCLIMORPH can have side effects.

Not all side effects reported for CYCLIMORPH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CYCLIMORPH, please consult your doctor, pharmacist or other health care professional for advice.

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

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

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

- Reduced platelet count (responsible for blood clotting and protecting from excessive bleeding),
- fitting (convulsions),
- inability of the liver to function well, abdominal pain, yellowish discoloration of eyes and skin (jaundice) (liver damage),
- lowered white blood cells,
- slow and shallow breathing,
- decreased consciousness,
- serious sleep disorder in which breathing repeatedly stops and starts,
- fast heartbeat,
- increased pressure in the brain,
- movements of the eyeballs into a fixed position, usually upwards (oculogyric crisis).
- severe stomach pain, which may reach to your back. This could be a sign of inflammation of your pancreas (pancreatitis).

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:

- Drowsiness, a spinning sensation,
- nausea, vomiting, constipation.

Less frequent side effects:

- Sleepless nights,
- confusion,
- depression (feeling down/ feeling low),
- hallucinations,
- headache, nervousness, dizziness,
- loss of appetite,
- irritation of the digestive tract,
- sharp pain under the rib cage in the upper right side or centre of the stomach (gallbladder spasm),
- restlessness,
- loose stools, upset stomach,
- dryness of mouth, nose and throat,
- difficult and painful urination,
- redness, swelling, pain, or burning at site of injection,
- blurred or double vision or other changes in vision,
- drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

Side effects with an unknown frequency:

- Nightmares,
- ringing in the ears and hearing voices or noises that are not there,
- uncontrolled muscle movements or trembling,
- lack of iron in the body which often cause shortness of breath, noticeable heartbeats, a pale complexion, tiredness and lack of energy (anaemia),
- lack of energy, a state of calm or sleep,

- lack of coordination, disorientation,
- anxiety,
- hives,
- pain in the upper middle of the stomach,
- tightness of the chest,
- increased appetite,
- eating disorders and muscular weakness,
- single cough or an episode of continuous coughing after injection in vein,
- narrower pupil of the eye,
- seeing things that are not actually there,
- low blood pressure that happens when standing after sitting or lying down or high blood pressure,
- low hormone levels leading to a decrease in male characteristics like male hair pattern, hair growth, voice etc in men after long term medical treatment,
- feeling or state of intense excitement and happiness,
- disorder that causes involuntary, unpredictable body movements (generalised chorea),
- pain from stimulus that does not normally provoke pain or abnormally heightened sensitivity to pain (hyperalgesia),
- excessive sweating,
- short term speech disorder,
- tingling or pricking (‘pins and needles’),
- injection site reactions including vein tracking.

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 “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/<+27 (0)11 239-6200

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

5. How to store CYCLIMORPH

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not freeze.

Protect from light.

Keep in original packaging until required for use.

Do not store in bathrooms.

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

What CYCLIMORPH contains

CYCLIMORPH 10:

The active substance per 1 ml ampoule is 10 mg of morphine tartrate and 50 mg of cyclizine tartrate.

The other ingredients are sodium metabisulphite, tartaric acid, water for injections.

CYCLIMORPH 15:

The active substance per 1 ml ampoule is 15 mg morphine tartrate and 50 mg cyclizine tartrate.

The other ingredients are sodium metabisulphite, tartaric acid, water for injections.

What CYCLIMORPH looks like and contents of the pack

CYCLIMORPH 10 is a clear, very slightly coloured solution.

1 x 1 ml clear, neutral, Type 1 glass ampoule with double white rings. 10 ampoules are placed in a plastic tray and then packed in an outer cardboard carton together with a leaflet.

CYCLIMORPH 15 is a clear, very slightly coloured solution.

1 x 1 ml clear, neutral, Type 1 glass ampoule with double red rings. 10 ampoules are placed in a plastic tray and then packed in an outer cardboard carton together with a leaflet.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/<+27 (0)11 239-6200

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05 February 2024

Registration numbers

CYCLIMORPH 10: B769 (Act 101/1965)

CYCLIMORPH 15: B770 (Act 101/1965)

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

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