

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **OFLAECT 15/30/60 INJECTION**

Dosage form and strength: Injection and 15 mg/mL, 30 mg/mL and 60 mg/2 mL

PATIENT INFORMATION LEAFLET FOR OFLAECT 15/30/60 INJECTION

SCHEDULING STATUS

S4

OFLAECT 15 INJECTION

OFLAECT 30 INJECTION

OFLAECT 60 INJECTION

Ketorolac tromethamine

OFLAECT INJECTION is sugar free

Read all of this leaflet carefully before you are given OFLAECT INJECTION

- 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 the leaflet

1. What **OFLAECT INJECTION** is and what it is used for
2. What you need to know before **OFLAECT INJECTION** is administered
3. How to receive **OFLAECT INJECTION**
4. Possible side effects
5. How to store **OFLAECT INJECTION**
6. Contents of the pack and other information

1. What OFLAECT INJECTION is and what it is used for

OFLAECT INJECTION belongs to a group of medicines known as nonsteroidal anti-inflammatory drugs (NSAIDs). **OFLAECT INJECTION** is used to relieve moderate pain after you had surgery. **OFLAECT INJECTION** will not be given to you for chronic painful conditions.

2. What you need to know before OFLAECT INJECTION is administered

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OFLAECT INJECTION should not be administered to you:

- if you are hypersensitive (allergic) to ketorolac tromethamine, other NSAIDs or any of the other ingredients of **OFLAECT INJECTION** (listed in section 6).
- if you have had a hypersensitivity reaction to ibuprofen, aspirin or other NSAIDs.
- if you are taking other NSAIDs such as oxpentifylline (to treat circulatory disease).
- if you are taking medicines used to treat gout such as probenecid.
- if you are taking medicines to treat nervous disorders such as lithium salts
- if you have previously had or have peptic ulcers (ulcer in your stomach or duodenum), bleeding in your stomach or perforation.
- if you have bleeding from a damaged blood vessel in the brain.
- if you have problems with bleeding or blood clotting disorders.
- if you are taking medicines to thin the blood (such as warfarin or low-dose heparin).
- if you suffer from kidney failure.
- if you suffer from liver failure.
- if you suffer from heart failure.
- if you are dehydrated or have lost a lot of blood.
- if you are pregnant or breastfeeding your baby.
- if you are a child under 16 years of age.

OFLAECT INJECTION should not be given to you:

- During labour and delivery when pregnant.
- Before undergoing an operation, or during the operation.
- As an epidural or intrathecal injection (via your spine).

Warnings and precautions

Tell your doctor or health care provider before being given OFLAECT INJECTION:

- if you have stomach problems, inflammatory bowel disease (e.g. ulcerative colitis or Crohn's disease) or are passing black tarry stools or blood.
- if you have problems with your kidneys or liver.

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- if you have nasal polyps, allergic swellings (of the skin, around the mouth, eyes, nose or the genitals) or constriction of the airways making breathing difficult.
- if you have asthma or a history of asthma.
- if you have ever had heart failure, high blood pressure or swelling of the hands, feet, ankles or lower legs.
- if you have problems with bleeding or blood clotting disorders.
- if you have lost a large amount of blood or had a blood transfusion recently.
- if you are dehydrated or recently suffered from diarrhoea or vomiting.
- if you are 65 years of age or older.
- If you develop a skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- If you have systemic lupus erythematosus (SLE) and mixed connective tissue disorders, there may be an increased risk of aseptic meningitis.
- if you have skin rash or itching after administration of **OFLAECT INJECTION**, your doctor will stop giving you **OFLAECT INJECTION** immediately.

Children and adolescents

This medicine is not for use in children less than 16 years of age.

Other medicines and OFLAECT INJECTION

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

Do not take:

- Oxpentifylline (to treat circulation disease).
- Other NSAIDs, like aspirin, ibuprofen or diclofenac.
- Medicines to stop your blood clotting, like warfarin, heparin or clopidogrel.
- Probenecid (to treat gout).
- Lithium (to treat nervous disorders).

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- Mifepristone (used to end early pregnancy).
- Ciclosporin (used to prevent organ rejection after transplant).
- Tacrolimus (used to treat atopic dermatitis (eczema)).

Tell your doctor or pharmacist if you are currently taking:

- An ACE inhibitor (medicine to treat high blood pressure) like enalapril, captopril, perindopril, etc.
- Water tablets (for high blood pressure) like furosemide.
- Digoxin (to treat heart problems).
- Methotrexate (used to treat skin problems, arthritis or cancer).
- A 'quinolone antibiotic' (for infections), like ciprofloxacin or moxifloxacin.
- Zidovudine (used to treat AIDS and HIV infections).
- Corticosteroids (used to treat inflamed areas of the body).

OFLAECT INJECTION with food, drink and alcohol

OFLAECT INJECTION should not be administered if you are suffering or recovering from alcoholism.

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 receiving **OFLAECT INJECTION**.

You should not be given **OFLAECT INJECTION** during pregnancy, breastfeeding and if you are planning to have a baby.

Driving and using machines

OFLAECT INJECTION may make you feel dizzy, tired or drowsy, you may also get headaches, visual disturbances, vertigo or have difficulty sleeping. If you experience any of these you should not drive or operate machines.

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OFLAECT INJECTION contains a small amount of ethanol (alcohol) per vial. This may be harmful if you are suffering or recovering from alcoholism.

Sodium chloride: This medicine contains less than 1 mmol sodium (23 mg) per <dosage unit><unit volume>, that is to say essentially 'sodium-free'.

3. How to receive OFLAECT INJECTION

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

You will not be expected to give yourself **OFLAECT INJECTION**. It will be given to you by a person who is qualified to do so. **OFLAECT INJECTION** will be given to you by injection into a muscle (such as into your arm) or into a vein.

The usual dose is between 10 mg and 30 mg. The dose may be lowered if you are an elderly person older than 65 years of age.

If you have the impression that the effect of **OFLAECT INJECTION** is too strong or too weak, tell your doctor or pharmacist.

If you receive more OFLAECT INJECTION than you should

Since your health care provider will administer **OFLAECT INJECTION**, he/she will control the dosage. However, in the event of an overdose your doctor will manage the overdose.

If you missed a dose of OFLAECT INJECTION

Since health care provider will administer **OFLAECT INJECTION**, it is unlikely that the dose will be missed.

4. Possible side effects

OFLAECT INJECTION can have side effects.

Not all side effects reported for **OFLAECT INJECTION** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **OFLAECT INJECTION**, please

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consult your health care provider for advice.

If any of the following happens, stop administration of **OFLAECT INJECTION** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of your 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 allergic reaction to **OFLAECT INJECTION**. 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:

- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds.
- Bleeding from your anus, seen as passing black sticky stools or bloody diarrhoea.
- Ulcers or holes forming in your stomach or gut. This may be seen as upset stomach with stomach pain, fever, feeling or being sick.
- Problems with your pancreas, seen as severe stomach pain which spreads to your back.
- Yellowing of your skin or the whites of your eyes (jaundice), feeling tired, loss of appetite.
- Difficulty breathing, including shortness of breath, wheezing or coughing.
- A severe rash that develops quickly, with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes.
- Problems passing urine with a feeling of fullness and a need to empty your bladder, but then difficulty in emptying it.
- Feeling depressed, seeing and hearing things that are not really there (hallucinations), seizures (fits).

Frequency unknown:

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- Changes in the way your heart beats, chest pain which may spread to your neck and shoulders and down your left arm.
- Fever, feeling or being sick, a stiff neck, headache, sensitivity to bright light and confusion.

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Inflammation and bleeding in the small blood vessels under the skin, appearing as blood spots on the skin.
- High blood pressure.
- Drowsiness, dizziness, headache.
- Sweating.
- Nausea and vomiting, diarrhoea, stomach pain, constipation, wind, indigestion, sore mouth.
- Weight gain.
- Swelling of your hands, legs and feet.
- Pain where the injection was given.

Less frequent:

- Blood problems, like anaemia, not enough platelets or changes to the number of white blood cells.
- Bleeding from your wound after an operation.
- Low blood pressure.
- Skin rashes, hives, itching, pimples.
- Feeling thirsty.
- Problems with your vision.
- Ringing in the ears (tinnitus), loss of hearing.
- Fever.

Frequency unknown:

- Feeling anxious, nervous, having difficulty sleeping, changes in your pattern of dreaming.
- Pins and needles or numbness of your hands and feet.
- Feeling off balance.

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- Muscle spasms or pains.
- Weakness or lack of energy.
- Dry mouth, changes in your sense of taste.
- Redness of the face and neck (flushing), or pale skin.
- Anaemia (not enough platelets or changes to the number of white blood cells).
- Oedema, systemic allergic reaction, asthma and nasal polyps
- Without appetite,
- Confusion and stimulation.
- Visual disturbances, inflammation of the optic nerves.
- shortness of breath (cardiac failure).
- Swelling up with blood or other fluids (as with congestion), Blood loss
- Female infertility
- Nosebleed
- Heartburn, stomach ache, feeling sick or being sick,
- Viral meningitis (as distinct from bacterial meningitis).

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 or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za>. or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of **OFLAECT INJECTION**.

5. How to store OFLAECT INJECTION

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Protect from light and moisture.

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- Keep the vial in the outer carton until required for use.
- Do not store in a bathroom.
- There are no special storage instructions for **OFLAECT INJECTION**.
- Do not use after the expiry date stated on the label / carton / vial.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- For single use only. Discard any unused ~~contents~~ portion.

6. Contents of the pack and other information

What OFLAECT INJECTION contains

- The active substance is ketorolac tromethamine.
- The other ingredients are citric acid monohydrate, ethanol absolute, ~~hydrochloric acid~~, sodium chloride, ~~sodium hydroxide~~ and water for injection.

What OFLAECT INJECTION looks like and contents of the pack

A clear and slight yellow solution.

Contents of the pack

OFLAECT 15 INJECTION: 2 mL Type-I, round amber colored tubular glass vial with 13 mm grey colored serum bromobutyl rubber stopper and 13 mm yellow flip off aluminium seal, packed in an outer carton.

Pack size: 5 vials.

OFLAECT 30 INJECTION: 2 mL Type-I, round amber colored tubular glass vial with 13 mm grey colored serum bromobutyl rubber stopper and 13 mm orange flip off aluminium seal, packed in an outer carton.

Pack size: 5 or 10 vials.

OFLAECT 60 INJECTION: 2 mL Type-I, round amber colored tubular glass vial with 13 mm grey colored serum bromobutyl rubber stopper and 13 mm dark blue flip off aluminium seal, packed in an outer carton.

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Pack size: 5 or 10 vials.

Not all pack sizes may be marketed.

Vials are kept in an outer carton until required for use.

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

Waterfall corporate campus,

Building no. 2, first floor,

74 waterfall drive,

Midrand 2066

Tell: 0126441220.

This leaflet was last revised in

08 August 2023

Registration number(s)

OFLAECT 15 INJECTION: 54/2.7/0286.

OFLAECT 30 INJECTION: 54/2.7/0287.

OFLAECT 60 INJECTION: 54/2.7/0288.

Access to the corresponding Professional Information

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