PATIENT INFORMATION LEAFLET

Information for the Patient about

OCTIN (Eye drops)

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

OCTIN containing 15 mg **ofloxacin** per 5 mℓ solution (Eye drops).

Read all of this leaflet carefully before you start using OCTIN:

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

The active substance is ofloxacin and each 5 mℓ solution contains 15 mg ofloxacin (0,3 % *m/v*).

Inactive ingredient is disodium edetate.

Contains benzalkonium chloride (0,01 % *m/v*) as preservative.

WHAT OCTIN IS USED FOR:

OCTIN is used to treat eye infections, such as conjunctivitis (pink eyes) or ulcers on the cornea (the part of the eye that covers the pupil), caused by bacteria.

BEFORE YOU USE OCTIN:

Do NOT use OCTIN:

- If you are allergic (hypersensitive) to ofloxacin, other fluoroquinolone antibiotics or their derivatives, benzalkonium chloride (the preservative), or to any of the inactive ingredients in **OCTIN**.
- While wearing soft contact lenses (see **"Take special care with OCTIN"**).
- If you are pregnant or breastfeeding your baby (see **"Pregnancy and breastfeeding"**).
- In children younger than 1 year of age, since safety and efficacy have not been established.
- If you are on medication for treatment of high blood pressure
- If you have mitral valve or aortic valve regurgitation (when your heart's mitral or aortic valve does not close tightly, causing blood to flow back into the heart instead of pumping out).

Take special care with OCTIN:

If you develop itching in or around the eye, swelling or puffiness of the eyelids with redness and severe tearing of the eye, stop using **OCTIN** and inform your doctor immediately, as these symptoms may indicate an allergic reaction to **OCTIN** (see **"POSSIBLE SIDE EFFECTS"**). You should not use **OCTIN** if you are allergic to other fluoroquinolone antibiotics (including ciprofloxacin, moxifloxacin, or levofloxacin).

Stop using **OCTIN** and inform your doctor immediately if you develop any skin rash with blister formation (see **"POSSIBLE SIDE EFFECTS"**). Such a skin rash may indicate a severe allergic reaction to **OCTIN**.

Stop using **OCTIN** and inform your doctor if your eye(s) is not better within 7 days of starting treatment with **OCTIN**.

Serious allergic reactions may require immediate emergency treatment. Oxygen and airway management should be given as clinically indicated.

Do not use **OCTIN** for prolonged periods of time, since your eyes may become inflamed or you may develop an infection with micro-organisms not sensitive to it. If you develop a pus-filled discharge from the eye, crusting of the eyelids or severe pain and swelling around the eye after you have used **OCTIN** for some time, please inform your doctor immediately.

If you are known to have an abnormal heart rhythm (including a slow heart rate), an inherited heart disorder, are taking medicines to treat abnormal heart rhythms or antidepressants (see **"Using OCTIN with other medicines"**), or if you previously had a heart attack or suffered from heart failure, please inform your doctor before you start using **OCTIN**.

OCTIN may affect your blood sugar (glucose) levels (see **"POSSIBLE SIDE EFFECTS"**). It may increase or decrease your blood sugar levels and is more likely to affect people that have been diagnosed with diabetes mellitus and are taking oral

antidiabetic medicine(s) or are using insulin. Very high or low blood glucose levels may result in coma and death. If you have been diagnosed with diabetes mellitus, you (in conjunction with your doctor) will have to monitor your blood glucose levels carefully while you are using **OCTIN**. Report to your doctor if you develop excessive hunger or thirst, frequent urination, fatigue, sweating, shaking or trembling, or if you feel faint or dizzy.

If you develop severe and persistent diarrhoea (runny stomach) during or after use of **OCTIN**, stop using **OCTIN** and inform your doctor immediately. Also inform your doctor immediately if you develop a pus-filled discharge from the nose, white spots inside the nose, mouth, or throat, or if your original symptoms become worse. This may be due to infection with organisms not sensitive to **OCTIN** and you may require alternative treatment.

If you have been diagnosed with reduced or poor liver or kidney function, myasthenia gravis (a nerve disorder characterised by muscle weakness), or glucose-6-phosphate dehydrogenase deficiency (an inherited disorder that affects your red blood cells), please inform your doctor before you start using **OCTIN**.

Elderly patients and people with impaired kidney function are more likely to experience headache, dizziness, convulsions (seizures), pins and needles, restlessness, agitation, anxiety or to hear or see things that are not real (see **"POSSIBLE SIDE EFFECTS"**). Stop using **OCTIN** and inform your doctor as soon as possible if you develop any of these side effects.

Do not wear your contact lenses while your eye(s) is infected and while you are using **OCTIN**. The preservative in **OCTIN** may damage soft contact lenses (see **"Do NOT use OCTIN"**).

You should not use **OCTIN** eye drops for an extended period of time, since the preservative may injure your cornea (the part of the eye that covers the pupil). Please inform your doctor if you have previously been diagnosed with conditions affecting your cornea or surface of the eye, as you will require special monitoring.

While using **OCTIN**, your eyes may become more sensitive to sunlight (see **"POSSIBLE SIDE EFFECTS"**). It is recommended that you wear sunglasses and/or avoid exposing your eyes to bright light.

Simultaneous use of **OCTIN** with medicines for high blood pressure treatment may precipitate acute kidney injury in patients, especially those with moderate to severe kidney problems and elderly patient.
Kidney function should be checked before starting treatment and monitored during treatment high blood pressure medication.

Tell your doctor if you have been diagnosed with mitral valve or aortic valve regurgitation (when your heart's mitral or aortic valve does not close tightly, causing blood to flow back into the heart instead of pumping out). Your doctor will perform a thorough examination of your heart, including an echocardiogram, since **OCTIN** should not be taken if you have mitral valve or aortic valve regurgitation (see **"Do not take OCTIN**).

Pregnancy and breastfeeding:

Do not use **OCTIN** while you are pregnant or breastfeeding your baby.

OCTIN is not recommended for breastfeeding women. There is a potential harm for feeding infants since ofloxacin and other quinolones are excreted in breast milk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using OCTIN.

Driving or using machinery:

Temporary blurred vision may occur after you have inserted **OCTIN** eye drops into your eye(s) (see **"POSSIBLE SIDE EFFECTS"**). If you experience blurred vision, you must wait until your vision clears before driving or using machinery.

Using other medicines with OCTIN:

Always tell your healthcare professional if you are taking any other medicine.

If you are using any of the following medicines or substances in combination with **OCTIN**, please discuss this with your treating doctor, as you may require dosage adjustments or other precautions:

- Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or diclofenac, for pain or inflammation, or theophylline for emphysema or bronchitis.
- Medicines to treat abnormal heart rhythms (see **"Take special care with OCTIN"**).

- Antidepressants (see **"Take special care with OCTIN"**).
- Antibiotics such as erythromycin.
- Medicine for high blood pressure.

If simultaneous use of these medicines is deemed necessary, they should be used with caution and the renal function should be monitored frequently throughout treatment.

HOW TO USE OCTIN:

Always use OCTIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Do not share medicines prescribed for you with other people.

Do not touch the applicator tip to any surface (including the eye).

Keep the eyes closed for 1 – 2 minutes after application.

OCTIN should be used for the complete treatment period.

Treatment should not exceed 10 days.

The usual dose is as follows:

Conjunctivitis (pink eyes):

Day 1 and 2:	1 drop every 2 – 4 hours.
Day 3 – 5:	1 drop every 6 hours.

Corneal ulcers:

Day 1 and 2:	1 – 2 drops into the affected eye(s) every 30 minutes while awake. 1 – 2 drops after 4 and 6 hours after retiring.
Day 3 – 7:	1 – 2 drops hourly while awake.
Day 7 – 9 or until completion:	1 – 2 drops 4 times daily.

Instructions for use:



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

If you use more OCTIN than you should:

If you accidentally instil more **OCTIN** eye drops than you should, you may experience redness of the eyes, increased tearing, swelling of the eyes, eyelid itching and a foreign body sensation in the eye. The eyes may be washed with lukewarm tap water. If you swallow **OCTIN**, you may experience palpitations or any of the other side effects listed below (see **"POSSIBLE SIDE EFFECTS"**).

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

If you forget to use OCTIN:

Always use **OCTIN** as prescribed. If you miss a dose, instil **OCTIN** as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not instil a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

OCTIN can have side effects.

Not all side effects reported for OCTIN are included in this leaflet. Should your general health worsen while using OCTIN, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side effects that you should bring to the attention of your doctor immediately include:

- Those that occur less frequently:

- Bleeding into the eye, severe itching in or around the eye that does not subside spontaneously, swelling or severe puffiness of the eyelids with redness and severe tearing of the eye (see **"Take special care with OCTIN"**).
- Swelling of the whole body, swelling of the tongue, constriction of the throat, and/or skin rash with hives and itching.
- Fainting spells, palpitations or irregular heartbeat, light-headedness, shortness of breath or difficulty breathing with or without exercise, or coughing when lying down or chest pain.
- Excessive hunger or thirst, frequent urination, blurred vision, fatigue, weakness, sweating, shaking or trembling, or if you feel faint or dizzy (especially if you have been diagnosed with diabetes mellitus), since this may be due to high or low blood sugar levels and may result in coma (see **"Take special care with OCTIN"**).
- Convulsions (seizures) (see **"Take special care with OCTIN"**).
- Any skin rash with blisters (see **"Take special care with OCTIN"**).

- Those that occur with unknown frequency:
  - Fever, chills, sore throat, coughing, pin point red spots on the skin, bleeding from the gums, easy bruising, shortness of breath with exertion, or ulcers on the skin.
  - Small blisters on the skin accompanied by bruising and red or purple patches on the skin.
  - Yellow discolouration of the skin or white of the eyes (jaundice) and/or pain over the liver area.

- Blood in the urine, painful urination, or pain in the flank or over the kidneys.

Side effects that you should report to your doctor as soon as possible include:

- Those that occur less frequently:
  - Hearing or seeing things that are not real, restlessness, agitation, anxiety, or confusion (see **"Take special care with OCTIN"**).
- Those that occur with unknown frequency:
  - Pins and needles, painful fingers or toes, tremor, unsteady gait, or disturbed sense of taste or smell.
  - Sensitivity of the eyes to light (see **"Take special care with OCTIN"**), double vision, or abnormal colour vision.
  - Pus-filled discharge from the eyes that does not improve with treatment.
  - Eye pain or foreign body sensation.
  - Swelling or puffy eyes.
  - Palpitations or abnormal heart rhythm.

Side effects that you should report to your doctor if they continue or become bothersome include:

- Those that occur frequently:
  - Headache, dizziness (see **"Take special care with OCTIN"**).
  - Transient eye irritation (including burning, dryness, tearing, stinging, redness, or itching) after instillation of **OCTIN**.

- Those that occur less frequently:
    - Depression.
- Those that occur with unknown frequency:
    - Sleep disturbances, nightmares.
    - Blurred vision after instillation (see **"Driving and using machinery"**).
    - Dry eyes.
    - Nausea, vomiting, loose stools, stomach pain, or loss of appetite.
    - Muscle or joint pain.

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

STORING AND DISPOSING OF OCTIN:

Preserve in tight, light-resistant container.

Store at or below 25 °C.

Do not use more than 30 days after opening.

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Return all unused medicine to your pharmacist.

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

Do not use after the expiry date stated on the packaging material.

PRESENTATION OF OCTIN:

Dropper bottles of 5 mℓ sterile solution.

IDENTIFICATION OF OCTIN:

A pale yellow, clear, sterile solution.

REGISTRATION NUMBER:

36/15.1/0002

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap

Mispel Street

Bellville

7530

RSA

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