Scheduling Status:

S3

OXYREST 5 mg tablets
Oxybutynin hydrochloride
Contains sugar (lactose monohydrate 106,5 mg per tablet)

Read all of this leaflet carefully before you start taking OXYREST

- 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.
- OXYREST 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 OXYREST is and what it is used for
2. What you need to know before you take OXYREST
3. How to take OXYREST
4. Possible side effects
5. How to store OXYREST
6. Contents of the pack and other information

1. What OXYREST is and what it is used for

OXYREST is a medicine which relaxes the smooth muscle found in the stomach and intestines, uterus, ducts carrying bile and ducts carrying urine from the kidneys to the bladder.

OXYREST is used for the relief of a compelling urge to urinate, frequent urination, incontinence, painful or difficult urination and bedwetting.

2. What you need to know before you take OXYREST

Do not take OXYREST:

- If you are known to be allergic (hypersensitive) to oxybutynin hydrochloride or any of the other ingredients of OXYREST tablets.
- If you have glaucoma (increased pressure in the eye).
- If you have an obstruction in the stomach or intestinal tract.

- If your intestinal tract is not functioning properly especially if you are elderly or debilitated.
- If you have ulcerative colitis which is an inflammatory bowel disease that causes inflammation and sores (ulcers) in the colon.
- If you have an autoimmune disease called myasthenia gravis which causes abnormal weakness of certain muscles.
- If you have an obstruction in the urinary tract.
- If you have lost a lot of blood.
- If you have a bladder condition where the bladder muscle is unable to contract.
- If you have an enlarged prostate.
- If you are pregnant or breastfeeding your baby.
- In children under the age of 5 years.

Warnings and precautions

Take special care with OXYREST:

- If the environmental temperature is high; especially when giving OXYREST to children and persons with fever. OXYREST reduces sweating and your body's ability to reduce your temperature; you may develop heat exhaustion.
- If you are taking certain medicines that may enhance the effects of OXYREST (see "Other medicines and OXYREST").
- If you are elderly or a child, you may be more sensitive to the effects of OXYREST.
- If you are elderly you are at risk of developing cognitive impairment (e.g. trouble remembering, concentrating and making decisions).
- If you develop diarrhoea while taking OXYREST, tell your doctor or healthcare provider as soon as possible.
- If you experience a faster than normal heart rate and suffer from hyperthyroidism (overactive thyroid), congestive heart failure, dysrhythmia (irregular heartbeat), coronary heart disease, high blood pressure or have had heart surgery, tell your doctor. OXYREST may worsen your condition.
- If you experience hallucinations, agitation, confusion or sleepiness during the first few months of OXYREST treatment or when your doctor increases your dose, tell your doctor as soon as possible.
- If you experience sudden blurred vision or eye pain, tell your doctor immediately.
- If you develop tooth decay/cavities, inflammation of the gums or oral thrush while taking OXYREST, tell your doctor.

- If you are suffering from acid reflux associated with a hernia or are taking medicines which can cause or exacerbate inflammation of the oesophagus (such as bisphosphonates used for osteoporosis), OXYREST may worsen your condition.

Other medicines and OXYREST:

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

OXYREST influences the functioning of the intestinal tract and may affect how other medicines work.

Tell your doctor if you are taking any of the following medicines, they may increase the effect of OXYREST if taken concurrently:

- medicines for Parkinson's disease (e.g. amantadine, biperiden, levodopa)
- antihistamines used for allergies
- medicines for certain mental illnesses (e.g. chlorpromazine, prochlorperazine, haloperidol, clozapine)
- medicines for depression (e.g. amitriptyline, imipramine, clomipramine, nefazodone)
- medicines for heart conditions (e.g. quinidine, digitalis, amiodarone, verapamil, diltiazem)
- certain antispasmodics (e.g. atropine, dipyridamole, hyoscine butylbromide)
- certain antibiotics (e.g. clarithromycin, erythromycin)
- antifungal medicines (e.g. ketoconazole, itraconazole, fluconazole)
- medicines for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir, saquinavir).

Tell your doctor if you are taking any of the following medicines, OXYREST may weaken their effect:

- medicines that increase bowel movement (e.g. cisapride, domperidone, metoclopramide)
- medicines for Alzheimer's disease (e.g. galantamine)
- medicines for myasthenia gravis a muscle disorder (e.g. pyridostigmine, neostigmine).

Taking OXYREST with food and drink

OXYREST can make you feel drowsy which is worsened by alcohol. You should not consume alcohol while taking OXYREST.

You should not consume grapefruit juice as it may increase the effect of OXYREST.

Pregnancy and breastfeeding

OXYREST is not recommended for use during pregnancy or breastfeeding (see Do not take OXYREST).

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking OXYREST.

Driving and using machines

OXYREST may cause blurry vision and drowsiness which may impair your ability to drive and operate machinery or performing work that requires mental alertness.

It is not always possible to predict to what extent OXYREST may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which OXYREST affects you.

OXYREST contains lactose monohydrate

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

3. HOW TO TAKE OXYREST

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

Always take OXYREST exactly as your doctor or pharmacist has you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for **adults** is one (1) tablet taken two to three (2-3) times a day; your doctor may increase your dose to a maximum of one (1) tablet taken four (4) times a day.

The usual dose for **elderly patients** is half (½) a tablet taken two (2) times a day; your doctor may increase your dose to one (1) tablet taken two (2) times a day.

The usual dose for **children older than 5 years** is half (½) a tablet taken two (2) times a day; your doctor may increase the dose to (1) tablet taken two to three (2-3) times a day.

Your doctor will tell you how long your treatment with OXYREST will last.

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

If you take more OXYREST than you should

You may experience symptoms such as increased body temperature, high blood pressure, hyperventilation, nausea and vomiting, a rash may appear on your face and torso; you may feel restless, confused, loss of coordination and muscle movements, paranoia and seizure. Severe overdosage can lead to coma, heart and respiratory failure.

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

It is important to seek medical help immediately.

If you forget to take OXYREST

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

OXYREST can have side effects. Children and elderly patients are at higher risk of experiencing OXYREST side effects.

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

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

- signs of a severe allergic reaction: swelling of your hands, feet, ankles, face, lips and mouth, difficulty breathing or swallowing, rash or itching, fainting
- reduced sweating leading to overheating in hot environments
- sudden blurred or loss of vision and/or eye pain.

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

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

Side effects experienced frequently:

- confusion, dizziness, headache, sleepiness
- blurred vision, dry eyes
- flushing which may be more marked in children, dry skin
- constipation, nausea, dry mouth, diarrhoea, vomiting
- difficulty in passing water (urine)

Side effects experienced less frequently:

- abdominal discomfort
- decreased appetite and weight loss
- difficulty swallowing

Side effects experienced at an unknown frequency:

- urinary tract infection
- allergic reaction which can include a skin rash, difficulty breathing or swallowing, swelling of the face, mouth, eyes, lips and tongue
- reduced breast milk
- nervousness and anxiety, seeing and hearing things that are not there (hallucinations), nightmares and paranoia
- difficulty in learning, remembering and problem solving especially in the elderly; depression; dependence on OXYREST especially in patients with a history of medicine or substance abuse); difficulty sleeping
- fits, drowsiness, disorientation, weakness
- increased pressure in the eye (glaucoma), dilation of the pupils, eyes are more sensitive to light
- abnormally fast heart rate, noticeably strong or irregular heartbeat
- formation of mucous plugs in the airway
- heartburn, difficulty in swallowing and talking, thirst, chest pain
- reduced sweating and heat stroke; skin is more sensitive to light; itchy, lumpy skin rash (urticaria)
- impotence.

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 or nurse. 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/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DR DU TOIT'S PAIN EXPELLER.

5. How to store OXYREST

Store all medicines out of the reach of children.

Store at or below 25 °C.

Keep in the original packaging to protect from light.

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

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 OXYREST contains

The active substance is oxybutynin hydrochloride.

The other ingredients are cellactose, cellulose 80, magnesium stearate and talc.

What OXYREST looks like and contents of the pack

OXYREST 5 mg tablet is a white, flat bevelled edge round odourless tablet, scored with a breakline on one side and with "5" embossed on the other side.

OXYREST is packaged in white plastic HDPE bottle with an aluminium induction seal and a white plastic screw cap containing 84 and 100 tablets.

Holder of Certificate of Registration

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