Dr. Reddy's Laboratories (Pty) Ltd.
APPROVED PATIENT INFORMATION LEAFLET:
TOPRAZ 4 & 5 (chewable tablets)
TOPRAZ 10 (film-coated tablets)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TOPRAZ 4, chewable tablet

TOPRAZ 5, chewable tablet

TOPRAZ 10, film-coated tablet

montelukast sodium

TOPRAZ 4 and 5: contains sugar (mannitol) and aspartame.

TOPRAZ 10: contains sugar (lactose).

Read all of this leaflet carefully before you start taking TOPRAZ

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

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1. What TOPRAZ is and what it is used for

The active ingredient, montelukast, is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).
Your doctor has prescribed TOPRAZ for the prevention and treatment of asthma.
In those adult asthmatic patients, in whom TOPRAZ is used, TOPRAZ may provide some symptomatic relief of seasonal allergic rhinitis (hay fever).
Seasonal allergic rhinitis occurs during specific seasons and symptoms may include sneezing, stuffy nose, runny nose and itching of the nose.

2. What you need to know before you take TOPRAZ

Do not take, or give your child TOPRAZ:

- if you or your child are allergic to montelukast or any of the other ingredients of TOPRAZ.

Do not give your child TOPRAZ 5 chewable tablets to take:

- if he/she is below the age of 6 years, as safety and efficacy have not been demonstrated.

Do not give your child TOPRAZ 10 film-coated tablets to take:

- if he/she is below the age of 15 years, as safety and efficacy have not been demonstrated.

Warnings and precautions

Take special care with TOPRAZ:

- You or your child should take your prescribed TOPRAZ daily even if you do not experience any symptoms.
- You or your child should carry on taking TOPRAZ during times when your illness seems to be worse and you must go and see your doctor if you feel the illness is not well controlled.
- You or your child should go and see your doctor if you experience that short

acting inhaled bronchodilators are needed more often than usual.

- You or your child should not use TOPRAZ on its own (monotherapy). It should be used along with other medicine for your asthma condition.
- You or your child should not use TOPRAZ on its own for exercise induced bronchospasms. If your doctor has prescribed a medicine to use before exercise, that medicine should be continued to be used unless the doctor recommends stopping.
- You or your child should not use TOPRAZ for an acute attack – you should always have your rescue medicine available.
- While your doctor may decide to gradually reduce your dose of inhaled corticosteroid under supervision, TOPRAZ should not be abruptly substituted for inhaled or oral corticosteroids. Do not stop giving or lower the dose of you or your child's other asthma medicines unless your doctor tells you to.
- It is important that you or your child take all asthma medicines prescribed by your doctor. TOPRAZ should not be replaced with other asthma medicines your doctor has prescribed.
- If you or your child's asthma is known to be made worse by aspirin and other non-steroidal anti-inflammatory drugs you should avoid these medicines while on treatment with TOPRAZ.
- Eosinophilia warning – If you or your child develop a combination of symptoms such as flu-like illness, pins and needles or numbness of your arms and legs, worsening of lung symptoms, and/or rash you should tell your doctor immediately.
- Behaviour and mood-related changes have been reported in patients taking TOPRAZ. Tell your doctor if you or your child experiences these changes while taking TOPRAZ (see Section 4, Possible side effects).

Use in children

TOPRAZ 4 chewable tablets are for children 2 to 5 years of age.

TOPRAZ 5 chewable tablets are for children 6 to 14 years of age.

Other medicines and TOPRAZ

Always tell your healthcare provider if you or your child are taking any other medicine.

(This includes complementary or traditional medicines).

In general, TOPRAZ does not interfere with other medicines that you or your child may be taking. It is important, however, to tell your doctor if you or your child are taking phenytoin, phenobarbitone or rifampicin, St. John's Wort, ketoconazole, itraconazole or voriconazole, paclitaxel, rosiglitazone or repaglinide, as well as other medications that you or your child are using or plan to use, including those obtained without a prescription.

If you are using any of these medicines, you may not be able to take TOPRAZ, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

TOPRAZ with food and drink

TOPRAZ can be taken with or without food.

Pregnancy and Breastfeeding

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 this medicine.

Do not use TOPRAZ if you are pregnant.

You should not breastfeed your baby while taking TOPRAZ.

Driving and using machines

TOPRAZ may cause drowsiness or dizziness and patients are advised not to drive or operate machinery while on this treatment.

TOPRAZ 4 and 5 contain mannitol and aspartame and TOPRAZ 10 contain lactose

If you or your child have been told by your doctor that you or your child have an intolerance to some sugars, contact your doctor before you or your child takes TOPRAZ.

TOPRAZ 4 & 5 contains mannitol which may have a laxative effect.

TOPRAZ 10 contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take TOPRAZ 10.

If you or your child has phenylketonuria (a rare inherited condition in which a baby is born without the ability to properly break down an amino acid called phenylalanine), you should note that the TOPRAZ 4 mg and 5 mg chewable tablets contain aspartame, which is a source of phenylalanine (1,2 mg per 4 mg chewable tablet and 1,5 mg per 5 mg chewable tablet). It may be harmful to patients with phenylketonuria as it contains aspartame.

3. HOW TO TAKE TOPRAZ

Always take TOPRAZ exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

You or your child should take TOPRAZ once a day with or without food, as prescribed by your doctor.

TOPRAZ 4 chewable tablets

Paediatric patients 2 to 5 years of age with allergic asthma:

The usual dose for paediatric patients 2 to 5 years of age is one 4 mg chewable tablet in the evening.

TOPRAZ 5 chewable tablets

Paediatric patients 6 to 14 years of age with allergic asthma:

The usual dose for paediatric patients 6 to 14 years of age is one 5 mg chewable tablet in the evening.

TOPRAZ 4 mg and 5 mg tablets have not been studied in seasonal allergic rhinitis in children with asthma.

TOPRAZ 10 film coated tablets

Adults and children 15 years of age and older with allergic asthma with or without seasonal allergic rhinitis:

The usual dose for adults 15 years of age and older is one 10 mg tablet in the evening.

If you have the impression that the effect of TOPRAZ is too strong or too weak, talk to your doctor or pharmacist.

It is important to take TOPRAZ for as long as your doctor has prescribed it in order to maintain control of your or

your child's asthma.

TOPRAZ can only prevent your asthma, if you continue to take it.

Do not share your or your child's medicines with any other person.

If you or your child take more TOPRAZ than you should

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

The most frequently occurring symptoms reported with overdosage in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, irritability, restlessness and tremor.

If you or your child forgets to take TOPRAZ

Try to take TOPRAZ as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily. Do not take a double dose to make up for forgotten individual doses.

If you or your child stops taking TOPRAZ

Do not stop taking TOPRAZ unless your doctor tells you or your child to.

4. Possible side effects

TOPRAZ can have side effects. Not all side effects reported for TOPRAZ are included in this leaflet.

Should you or your child's general health worsen or if you or your child experience any untoward effects while taking TOPRAZ, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Allergic reactions (including itching, skin rash, inflammation of the blood vessels or sensitivity to the sun) which may develop into serious reactions with difficulty

in breathing, shortness of breath or fall in blood pressure and shock.

- Swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Yellowing of the skin and eyes which is called jaundice.

These are all very serious side effects. If you or your child have them, you or your child may have had a serious allergic reaction to TOPRAZ. You or your child may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you or your child notice any of the following:

- Bruising and bleeding tendency.
- Increase in certain white blood cells (eosinophils) and possible inflamed blood vessels throughout the body (systemic vasculitis). This rarely happens in people with asthma who take TOPRAZ. This usually, but not always, happens in people who also take a steroid medicine by mouth that is being stopped or where the dose is being lowered.
- Feel like harming or killing yourself/his or herself.
- Have abnormal dreams, stutter, seeing, feeling or hearing things that are not real, feeling agitated, including aggressive behaviour or anxious, feeling sad or disorientated, memory problems, obsessive-compulsive symptoms, cannot sleep, irritable or restless, sleep walking, uncontrolled muscle movements.

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

Tell your doctor if you or your child notice any of the following:

Frequent side effects:

- Upper respiratory tract infections.
- Headache.
- Stuffy nose, cough, flu-like symptoms.
- Rash.
- Feeling weak and tired, fever, increased sweating, trauma (emotional stress), thirst.
- Increase in liver enzymes (picked up in blood tests).

Less frequent side effects:

- Feeling drowsy or dizzy, numbness, "pins and needles", fits.
- Eye problems (abnormal contraction of the eyelid muscles, dilated pupils).
- Feeling or sensation of spinning (a specific kind of dizziness).
- Heart beats too hard or too fast, chest pain.
- Nose bleeding, swelling (inflammation of the lungs).
- Feeling sick (nausea), throwing up (vomiting), loose stools (diarrhoea), stomach pain, irregular bowel movement, dry mouth, indigestion, gas, increased saliva.
- Liver problems.
- Itching, "hives", skin inflammation resulting in reddish, painful, tender lumps, swelling, bruising.
- Sore stiff joints, muscle pain and cramps.
- Bedwetting in children.
- Swelling, high fever.
- Changes in blood counts (picked up in blood tests).

If any of these side effects get serious, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. Health care providers are asked to report any suspected adverse reactions 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.

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

5. How to store TOPRAZ

Store at or below 25 °C, protected from moisture and light.

Keep the blisters in the carton until required for use.

Keep the HDPE containers tightly closed.

Do not store in bathrooms.

Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

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

Keep all medicines out of the reach and sight of children.

6. Contents of the pack and other information

The active substance is montelukast.

TOPRAZ 4: Each chewable tablet contains montelukast sodium equivalent to montelukast 4 mg.

TOPRAZ 5: Each chewable tablet contains montelukast sodium equivalent to montelukast 5 mg.

TOPRAZ 10: Each film-coated tablet contains montelukast sodium equivalent to montelukast 10 mg.

The other ingredients in TOPRAZ 4 and TOPRAZ 5 chewable tablets are mannitol, hydroxypropyl cellulose,

croscarmellose sodium, ferric oxide, cherry flavour, aspartame, microcrystalline cellulose, and magnesium stearate.

All chewable tablets contain sugar (mannitol).

Chewable 4 and 5 mg tablets: Contain aspartame.

The other ingredients in TOPRAZ 10 film-coated tablets are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, hypromellose, titanium dioxide, macrogol, iron oxide yellow, iron oxide red and iron oxide black.

Contains sugar (lactose).

What TOPRAZ looks like and contents of the pack

TOPRAZ 4: light pink to pink coloured, speckled, oval shaped, biconvex tablets debossed with 'MTS' on one side and '4' on the other side.

TOPRAZ 5: light pink to pink coloured, speckled, round shaped, biconvex tablets debossed with 'MTS' on one side and '5' on the other side.

TOPRAZ 10: brown coloured, rounded square-shaped, film-coated tablets debossed with 'MTS' on one side and '10' on the other side.

TOPRAZ 4, 5 and 10 are available in packs of 14/28/30/100 tablets in white HDPE containers with white plastic lids and in packs of 10 tablets in blisters, one side silver coloured aluminium foil and the other side blue coloured aluminium foil with a polyethylene layer containing dessicant.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

Morningside

Sandton

2057

This leaflet was last revised in

24 November 2022

Registration numbers

TOPRAZ 4: 43/10.2.2/0785

TOPRAZ 5: 43/10.2.2/0786

TOPRAZ 10: 43/10.2.2/0787

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website:

http://www.drreddys.co.za