PATIENT INFORMATION LEAFLET FOR FEXXTAB 120 and 180

SCHEDULING STATUS

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FEXXTAB 120 and 180 film coated tablets

Fexofenadine Hydrochloride

FEXXTAB 120 contains sugar (lactose, 191,34 mg).

FEXXTAB 180 contains sugar (lactose, 287,00 mg).

Read all of this leaflet carefully because it contains important information for you.

FEXXTAB is available without a doctor's prescription for you to treat a mild illness.

Nevertheless, you still need to use FEXXTAB carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FEXXTAB with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What FEXXTAB is and what it is used for

FEXXTAB contains fexofenadine hydrochloride, which belongs to a group of medicines called antihistamines.

FEXXTAB is used in adults and adolescents of 12 years and older to relieve the symptoms of:

- FEXXTAB 120:Hay fever (seasonal allergic rhinitis), such as sneezing, itchy, runny or blocked nose and red, itchy and watery eyes.
- FEXXTAB 180: Long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes.

2. What you need to know before you take FEXXTAB

***Do not take FEXXTAB*:**

- If you are hypersensitive (allergic) to fexofenadine hydrochloride or any of the other ingredients of FEXXTAB (listed in section 6).
- If you are pregnant or breastfeeding since the safety has not yet been established.

Warnings and precautions

Take special care with FEXXTAB and talk to your doctor:

- If you have problems with your liver or kidneys.
- If you are elderly.
- If you have heart problems, as FEXXTAB, like other antihistamines may cause your heart to beat faster (tachycardia) or you feel your heart beating (palpitations).

If any of these apply to you, or you are not sure, please inform you doctor or pharmacist before taking FEXXTAB.

Children and adolescents

Do not give FEXXTAB to children under the age of 12 years because the safety and effectiveness of FEXXTAB in this age group has not been studied.

Other medicines and FEXXTAB

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is particularly important for the following medicines:

- Erythromycin (an antibiotic) and ketoconazole (a treatment for fungal infections) because these medicines may increase the amount of FEXXTAB in your blood.
- If you are taking apalutamide (a medicine to treat prostate cancer), as it may decrease the effect of FEXXTAB.
- Indigestion remedies containing aluminium and magnesium may affect the action of FEXXTAB by lowering the amount of medicinal product absorbed. It is recommended that you leave about 2 hours between the time that you take FEXXTAB and your indigestion remedy.

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 taking FEXXTAB.

Pregnancy:

You should not take FEXXTAB if you are pregnant because the safety and effectiveness of FEXXTAB has not been studied in pregnant women.

Breastfeeding:

FEXXTAB may be present in breastmilk, therefore you should not take FEXXTAB if you are breastfeeding your baby.

Fertility:

It is not known whether FEXXTAB affects your ability to have a baby.

Driving and using machines

FEXXTAB is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery. If you take alcohol or other sedatives, these effects may be worsened.

Important information about some of the ingredients of FEXXTAB

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

3. How to take FEXXTAB

Do not share medicines prescribed for you with any other person.
Always take FEXXTAB exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents aged 12 years and over

The usual dose for adults and children aged 12 years and older is:

- For hay fever (seasonal allergic rhinitis): One 120 mg tablet daily.
- For long term allergic skin reactions (chronic idiopathic urticaria): One 180 mg tablet daily.

The tablets should be swallowed with liquid and should not be chewed.
FEXXTAB should not be broken because the coating is intended to make sure that the medicines are released over a long period.

If you have the impression that the effect of FEXXTAB is too strong or too weak, tell your

doctor or pharmacist.

If you take more FEXXTAB 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 common signs of overdose are dizziness, drowsiness and dry mouth.

If you forget to take FEXXTAB

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take FEXXTAB at the next regularly scheduled time.

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

If you stop taking FEXXTAB

Tell your doctor or pharmacist if you want to stop taking FEXXTAB before you have finished your course of treatment. If you stop taking FEXXTAB earlier than planned, your symptoms may return. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

FEXXTAB can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, 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 FEXXTAB. 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:

- Changes in the way your heart beats, for example, if you notice it beating faster or irregular.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache, drowsiness, dizziness,
- Nausea (feeling sick).

Less frequent side effects:

- Chest tightness, swelling, flushing,
- Tiredness, difficulty sleeping (insomnia), nervousness and sleep disorders or paranoia (nightmares/excessive dreaming),
- Skin rash and itching, hives.

Side effects with unknown frequency:

- Blurred vision
- Fast heart rate or a sensation that your heart is racing, pounding, fluttering or skipping a beat.

- Diarrhoea.

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/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FEXXTAB.

5. How to store FEXXTAB

Store all medicines out of reach of children.

Store at or below 30 ºC.

Protect from light and moisture.

Do not take after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What FEXXTAB contains:

FEXXTAB 120: Each film coated tablet contains 120 mg fexofenadine hydrochloride.

FEXXTAB 180: Each film coated tablet contains 180 mg fexofenadine hydrochloride.

The other ingredients are colloidal anhydrous silica, croscarmellose sodium, lactose, magnesium stearate, povidone and pregelatinised maize starch.

The tablet coating contains Opadry pink which consists of hypromellose, titanium dioxide,

macrogol, iron oxide yellow and iron oxide red.

What FEXXTAB looks like and contents of the pack

FEXXTAB 120: Peach coloured, oblong shaped, biconvex film coated tablets with both sides plain.

FEXXTAB 180: Peach coloured, oblong shaped, biconvex film coated tablets with both sides plain.

Blister strips of rigid, PVC film coated with clear PVdC and printed aluminium foil.

Blister strips containing 10 tablets each are packed in an outer carton.

Pack size: 10 and 30 film coated tablets.

Holder of certificate of registration

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