PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

FENOZYD 10 mg tablets

Baclofen

Sugar free.

Read all of this leaflet carefully before you start taking FENOZYD.

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

1. What FENOZYD is and what it is used for

FENOZYD contains the active ingredient baclofen, which is a muscle relaxant medicine. It is used to reduce and relieve the excessive tension in your muscles (spasms) occurring in various illnesses, such as spinal cord diseases, cerebrovascular accidents and other nervous system disorders.

2. What you need to know before you take FENOZYD

FENOZYD should not be administered to you

- If you are hypersensitive (allergic) to baclofen or any of the other ingredients of FENOZYD (see section 6).
- If you suffer from porphyria.

Warnings and precautions

Take special care with FENOZYD:

- If you have a history of alcohol abuse or you drink excessive amounts of alcohol.
- If you have high blood pressure and if you are taking treatment for your high blood pressure.
- If you suffer from a mental illness (including schizophrenia, depression or mania).
- If you have been diagnosed with Parkinson's disease.
- If you have a history of drug abuse.
- If you have epilepsy (fits/seizures).
- If you have had a stroke.
- If you have difficulty breathing.
- If you have any liver problems.
- If you are an elderly person (over 65 years of age).
- If you suffer from or have a stomach ulcer.
- If you suffer from any kidney problems.
- If you have difficulty urinating.
- If you have diabetes; your doctor may want to monitor your condition.

Some people being treated with baclofen have had thoughts of harming or killing themselves or have tried to kill themselves. Most of these people also had depression, had been using alcohol excessively or were prone to having thoughts of killing themselves. If you have thoughts of harming or killing yourself at any time while taking FENOZYD, speak to your doctor straightaway or go to a hospital.

Also, ask a relative or close friend to tell you if they are worried about any changes in your behaviour and ask them to read this leaflet.

Your doctor may do regular blood tests to monitor your liver function.

If you are going to have an operation when you will have a general anaesthetic, tell the doctor or dentist that you are taking FENOZYD.

Children and adolescents

There are very limited clinical data on the use of FENOZYD in children under the age of one year. Your doctor will determine if your child should take FENOZYD.

Other medicines and FENOZYD

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

Tell your doctor or pharmacist if you are currently using:

- Other muscle relaxants, such as tizanidine (used to relax your muscles), it may intensify the sedative effect of FENOZYD.
- Opiates, including morphine and fentanyl (used to relieve pain), it may result in a decrease in your blood pressure.
- Lithium (used to treat mood disorders or depression), may intensify uncontrolled body movements.
- Antidepressant medicines (used to treat depression), it may intensify the effect of FENOZYD.
- Antihypertensive medicines (used to treat high blood pressure), it may result in a further decrease in blood pressure.
- Levodopa or carbidopa (used to treat Parkinson’s disease), it may intensify the symptoms of Parkinson’s disease together with hallucinations, nausea, irritation and anxiousness.

- Medicines which affect your kidneys, it may reduce the excretion of FENOZYD and lead to toxic levels in your body.

FENOZYD with food, drink and alcohol

Do not drink alcohol while you are taking FENOZYD.

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 healthcare provider for advice before taking FENOZYD.

There are no adequate and well-controlled studies in pregnant women. Do not take FENOZYD during pregnancy.

If you take FENOZYD during pregnancy, your unborn baby will also be exposed to FENOZYD. After birth, your baby may develop withdrawal symptoms, such as convulsions.

Although very small amounts of FENOZYD pass into breast milk, your doctor will discuss with you whether you should breastfeed while taking FENOZYD.

Driving and using machines

FENOZYD can cause side effects, such as dizziness, sedation, drowsiness, vision impairment and poor concentration, which may affect your ability to drive a vehicle or operate machinery. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how FENOZYD affects you.

3. How to take FENOZYD

Do not share medicines with any other person.

Always take FENOZYD exactly as your doctor or pharmacist has told you. Check with your doctor

or pharmacist if you are not sure.

Your doctor will determine the correct dose for you or your child.

You will be started on a low dose, and this will be increased gradually over a few days, under the supervision of your doctor, until you are taking the dose which is right for you.

If the starting dose is too high, or if the dose is increased too quickly, you may experience side effects, particularly if you are an elderly patient (over 65 years of age), have kidney problems or if you have had a stroke.

Do not exceed the recommended dosage.
You should take the tablets with food or a milk drink, especially if you feel sick when you take them.
If you have the impression that the effect of FENOZYD is too strong or too weak, tell your doctor or pharmacist.

If you take more FENOZYD than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Take this leaflet and the remaining FENOZYD tablets with you so the doctor will know what you have taken.

If you forget to take FENOZYD

Do not take/receive a double dose to make up for forgotten individual doses. Take the next dose at the regularly scheduled time.

If you stop taking FENOZYD

Do not stop taking FENOZYD unless your doctor tells you to. If you stop taking FENOZYD without gradually reducing the dose, you may experience withdrawal symptoms, such as anxiety, feeling confused, hallucinations, mental disorders, convulsions, changes in the way your heart beats, increased body temperature, increased spasticity, muscle breakdown and/or involuntary movements.

Your doctor will tell you how to stop taking FENOZYD.

4. Possible side effects

FENOZYD can have side effects.

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

If any of the following happens, stop taking FENOZYD 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 allergic reaction to FENOZYD. 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:

Side effects occurring frequently

- difficulty breathing
- changes in the way your heart functions (low cardiac output).

The following side effects can occur, but the frequency is not known

- trouble breathing while you are sleeping (sleep apnoea syndrome)
- changes in the way your heart beats, such as beating slower than normal.

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

Tell your doctor if you notice any of the following:

Side effects occurring frequently

- sedation, drowsiness, dizziness
- dry mouth
- light-headedness, headache
- tiredness
- feeling confused or depressed
- difficulty sleeping (insomnia), nightmares
- mood changes with extreme excitement
- muscle weakness, muscle pain, lack of muscle control or coordination
- tremor (uncontrolled shaking)
- rapid or uncontrolled eye movements
- blurred vision, problems with your eyesight
- low blood pressure (dizziness or light-headedness)
- nausea (feeling sick), vomiting (being sick), diarrhoea, constipation, dry heaving (retching), stomach problems
- excessive sweating
- frequent urination, difficult or painful urination, involuntary urination.

Side effects occurring less frequently

- paraesthesia (pins and needles, numbness of your skin)
- difficulty speaking
- disturbed sense of taste

- pain in your stomach area
- changes in liver function, your doctor may do regular blood tests to monitor your liver function
- inability to empty your bladder
- difficulty getting or maintaining an erection (if you are male)
- ringing in your ears (tinnitus).

The following side effects can occur, but the frequency is not known

- hives
- symptoms caused by stopping treatment suddenly (drug withdrawal syndrome).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FENOZYD.

5. How to store FENOZYD

- Store at or below 25 °C.
- Protect from light.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the container/label/carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FENOZYD contains

Each tablet contains 10 mg baclofen.

The other ingredients are anhydrous calcium hydrogen phosphate, magnesium stearate, microcrystalline cellulose, povidone, pregelatinised starch and sodium starch glycolate.

What FENOZYD looks like and contents of the pack

White to off-white coloured, round shaped, biconvex, uncoated tablets with bevelled edges, a score line on one side and a “10” debossed on the other side. The tablet can be divided into equal halves.

Clear transparent PVC/PVDC aluminium blister strips containing 10 tablets.

Pack size: 30 tablets.

Holder of certificate of registration

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0157

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Not applicable.

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