1.3.2. Proposed Patient Information Leaflet

SCHEDULING STATUS

S5

SEDABARB 30 mg TABLETS

Phenobarbitone

Contains Sugar: Lactose monohydrate 17,9 mg

Read all of this leaflet carefully before you start taking SEDABARB

- 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.
- SEDABARB 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 the leaflet

1. What SEDABARB is and what it is used for

Phenobarbitone belongs to a group of medicines called barbiturates.

Phenobarbitone helps in the treatments of recurrent fits and as a general sedative.

2. What you need to know before you take SEDABARB

Do not take SEDABARB:

- if you are hypersensitive (allergic) to phenobarbitone, other barbiturates or any of the ingredients of SEDABARB listed in section 6.

- If you have porphyria (a genetic or inherited disorder of the red blood pigment haemoglobin).

Warnings and precautions

Take special care with SEDABARB

- when prolonged use of SEDABARB may lead to dependence.
- when abrupt withdrawal of SEDABARB happens this may result in seizures and confusion.
- If you experience increased sedation, this may be reduced with prolonged use of SEDABARB.
- when SEDABARB is administered to the elderly, the dosage should be reduced until tolerance is assessed.
- if you have kidney problems.
- if you have breathing difficulties.

Other medicines and SEDABARB

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines).

- If you are on sedatives to calm your nerves.
- If you on medicines used to prevent or relieve symptoms of some types of allergies.
- Medicines to treat depression.
- If you are taking oral contraceptives.

SEDABARB with food, drink and alcohol

You should not drink alcohol while taking this medicine.

Pregnancy, breast-feeding and fertility

Pregnancy

What you should know about the use of antiepileptic drugs in pregnancy If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby. If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before

you become pregnant. You should not stop your treatment without discussing this with your doctor. Suddenly stopping may lead to breakthrough seizures which may harm you and your unborn baby. It is important that your epilepsy is well controlled.

Taking Phenobarbitone during pregnancy increases the chance that the baby may have a physical birth abnormality. Studies with women treated with Phenobarbitone for epilepsy have shown that around 6-7 babies in every 100 will have serious physical birth abnormalities. This compares to 2-3 babies in every 100 born to women who don't have epilepsy.

The most common types of serious physical birth abnormalities (major congenital malformations) reported for Phenobarbitone include heart defects and, less commonly, cleft lip and palate defects.

Studies have found that the risk of physical birth abnormalities increases with increasing dose of Phenobarbitone. Therefore, your doctor will prescribe you the lowest effective dose. Taking more than one epilepsy medicine at the same time may also increase the risk of physical birth abnormalities. Where possible, your doctor will consider using one epilepsy medicine only to control your epilepsy.

Your doctor may advise you to take folic acid if you're planning to become pregnant and while you're pregnant. Your doctor may adjust your Phenobarbitone dose when you take folic acid. This is because folic acid supplements may affect your blood levels of Phenobarbitone. Some studies observed that taking Phenobarbitone during pregnancy increases the chance
that the baby may have problems affecting learning and thinking abilities. Studies have also shown that babies born to mothers who have taken Phenobarbitone are born of smaller size than expected compared to children of mothers who did not take Phenobarbitone.

Women of child-bearing potential/Contraception

If you are a woman of childbearing age you should use effective contraception during treatment with Phenobarbitone and for two months after treatment. Phenobarbitone may affect how hormonal contraceptives, such as the contraceptive pill, work and make them less effective at preventing pregnancy.

Talk to your doctor, who will discuss with you the most

suitable type of contraception to use while you are taking Phenobarbitone. If you are a woman of childbearing age and are planning a pregnancy, talk to your doctor before you stop contraception and before you become pregnant about switching to other suitable treatments in order to avoid exposing the unborn baby to Phenobarbitone.

Breast-feeding

If you are taking Phenobarbitone Tablets, do not breastfeed, as the medicine will pass into the breast milk and may harm the baby.

Driving and using machines

Patients should ensure that they do not drive vehicles or operate machinery where loss of concentration could lead to injury.

SEDABARB contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. HOW TO TAKE SEDABARB

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

Check with your doctor or pharmacist if you are not sure.

For Epilepsy - 1 tablet morning and at night.

For Hypnotic - 1 tablet to be taken one hour before bedtime.

For Sedative - 1 tablet to be taken three times a day.

If you take more SEDABARB than you should

If you take more SEDABARB than you should, you may experience an increase in side effects listed below (see **section 4**).

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

If you forget to take SEDABARB

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

If you stop taking SEDABARB

If you stop taking the tablets you may develop withdrawal effects such as sleeplessness, anxiety, dizziness, fits and confusion.

4. POSSIBLE SIDE EFFECTS

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

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

- Breathing difficulties (respiratory depression).
- Allergic skin reaction
- Being restless, disorientated and confused.

These are all very serious side effects. If you have them, you may have had a serious reaction to SEDABARB. 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:

- Difficulty breathing.
- Less urine than is normal for you.

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

Tell your doctor if you notice any of the following:

<u>Frequency unknown side effects:</u>

- loss of muscle co-ordination

- excitement
- disorientation
- restlessness
- mental confusion
- depression
- jerky movements of the eyes
- hyperexcitability may occur in children
- dizziness
- severe respiratory insufficiency
- abnormally slow and shallow breathing
- liver disease
- skin rashes
- liver and kidney function

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 **SEDABARB.**

5. HOW TO STORE SEDABARB

Store all medicines out of reach of children.

- Keep in a cool, dry place, at or below 25 ^{o}C.
- Protect from light / moisture
- Do not store in a bathroom
- Do not use medicine after the expiry date stated on the label.

- 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 SEDABARB contains

Each tablet contains:

Phenobarbitone	30 mg
Contains Sugar: Lactose monohydrate	17,9 mg

The other ingredients are:

Flowlac 100, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

What SEDABARB looks like and contents of the pack

White normal biconvex tablet, with a breakline on one side, 5,5mm in diameter.

Amber PVC containers of 100, 500, 1000 and 5000 tablets.

White polypropylene securitainers of 42, 100 and 1000 tablets.

Patient ready packs of different pack sizes.

Holder of Certificate of Registration

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This leaflet was last revised in

07 November 2022

Registration Number

E/2.3/107 (South Africa)

B9315035 (Botswana)