1.5.5. 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.

- Hyperkinetic children, severe hepatic or renal function impairment.
- If you have porphyria (a genetic or inherited disorder of the red blood pigment haemoglobin).
- have **severe breathing difficulties.**
- have **severe kidney** or **liver** disease.

Warnings and precautions

Take special care with SEDABARB

Talk to your doctor or pharmacist before taking

Phenobarbitone tablets if you:

• or the person taking these tablets are **young, run down, senile** or have a **history of drug abuse** or **alcoholism**

• have **kidney** or **liver** problems

• have **breathing difficulties**

• have **severe** or **long term pain**.

A small number of people being treated with antiepileptics

such as phenobarbital have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Other medicines and SEDABARB

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

(This includes all complementary or traditional medicines).

• disopyramide and quinidine (to **treat irregular heartbeats**)

• chloramphenicol, doxycycline, metronidazole, rifampicin, telithromycin, griseofluvin, itraconazole, posaconazole, voriconazole, abacavir, amprenavir, lopinavir, indinavir, darunavir, nelfinavir and saquinavir (to **treat infections**).

• medicines used to thin the blood such as **warfarin**

• mianserin, paroxetine, MAOI or tricyclic antidepressants or St John's wort (*Hypericum perforatum*) a herbal remedy (to **treat depression**)

• oxcarbazepine, primidone, phenytoin, sodium valproate, carbamazepine, lamotrigine, tiagabine, zonisamide, ethosuxamide and vigabatrin (to **treat epilepsy**)

• chlorpromazine, thioridazine, haloperidol, aripiprazole and clonazepam (to **treat mental illness**)

• felodipine, verapamil, diltiazem, nimodipine, nifedipine, metoprolol, timolol and propranolol (to **treat high blood pressure**)

• digitoxin or eplerenone (to **treat certain heart conditions**)

• ciclosporin or tacrolimus (to **prevent organ transplant rejection**)

• **steroids** such as hydrocortisone or prednisolone

• folic acid or vitamin D (**supplements**)

• toremifene, gestrinone, irinotecan or etoposide (to **treat some cancers**)

• **methadone** (used in severe pain or drug addiction)

• **oral contraceptives** (talk to your doctor about the best method of contraception for you) or tibolone (female hormone)

• **levothyroxine** (thyroid hormone)

• montelukast or theophylline (to **treat asthma**)

• tropisetron and aprepitant (to **treat nausea and vomiting**)

• **memantine** (to treat dementia)

• **methylphenidate** (to treat attention deficit disorder)

• **sodium oxybate** (to treat narcolepsy).

SEDABARB with food, drink and alcohol

You should not drink alcohol while taking this medicine.

Pregnancy, breast-feeding and fertility

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:

• **Allergic reaction**: Skin rash, fever, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

• **Blood**: Altered numbers and types of blood cells, if you notice increased bruising, nosebleeds, sore throats or infections, you should tell your doctor who may want to perform a blood test.

• **Muscle, bone and connective tissue:** Problems with inflammation of tendons (e.g. Dupuytren's contracture of the hand, frozen shoulder), joint pain (arthralgia), bone softening and bone disease. There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on longterm antiepileptic medication, have a history of osteoporosis, or take steroids.

• **Reproductive system:** Scar tissue formation in the penis that can cause various penis problems (Peyronie's disease of the penis).

• **Mental health:** Restlessness and confusion in the elderly, unusual excitement, depression, memory impairment, hallucinations.

• **Nervous system:** Hyperactivity, behavioural disturbances in children, jerky movements, jerky eye movements, drowsiness, lethargy.

• **Heart:** Low blood pressure.

• **Lungs:** Difficulty breathing.

• **Liver:** Inflammation of the liver (hepatitis), damaged bile system (cholestasis) - seen as yellowing of skin and whites of eyes.

• **Kidneys:** Changes in the amount or need to pass water.

• **Skin:** Rashes, erythema multiforme (circular,irregular red patches), lumps in the armpits or groin area. Potentially life-threatening skin rashes (Stevens-Johnson syndrome - severe skin rash with flushing, fever, blisters or ulcers and toxic epidermal necrolysis - severe rash involving reddening, peeling and swelling of the skin that resembles severe burn

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.
- Allergic skin reaction.
- Being restless, disorientated and confused.
- Changes in the amount or need to pass urine.

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

Tell your doctor if you notice any of the following:

Frequency unknown side effects:

- 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
- Low blood pressure

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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