PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Schedule 2

SIBELIUM® T 5 mg tablets

SIBELIUM® 10 mg tablets

Flunarizine Hydrochloride

Contains sugar (lactose)

Read all of this leaflet carefully before you start taking SIBELIUM

SIBELIUM is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SIBELIUM carefully to get the best results from it

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

What is in this leaflet:

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

1. What SIBELIUM is and what it is used for:

SIBELIUM is used to:

- prevent migraine attacks in adults and children
- relieves the dizziness and spinning sensation ("vertigo') caused by inner ear conditions, in adults.

What you need to know before you take SIBELIUM

Do not take SIBELIUM if:

- you know that you are hypersensitive (allergic) to flunarizine or any of the other ingredients of SIBELIUM;
- if you have depressive illness or have a history of recurrent depression;
- if you have suffered or are now suffering from Parkinson's disease or a similar disease.

Warnings and special precautions:

Talk to your doctor or pharmacist before taking SIBELIUM tablets, if

- you start to feel tired while taking the tablets. Tell your doctor as this can be an effect of the tablets. Your doctor may stop your treatment, or reduce your dose
- you take more tablets than recommended, this will increase the risk of side-effects
- women who have had depressive illness may be more likely to become depressed again when using SIBELIUM long term
- you are elderly, as the tablets may give rise to depressive illness, Parkinson's disease or a similar disease.

Important information about some of the ingredients of SIBELIUM

SIBELIUM contains “lactose” (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking SIBELIUM.

Other medicines and SIBELIUM

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

If you are on SIBELIUM, alcohol, sleeping pills and tranquilisers can bring on sleepiness and drowsiness faster. You should limit the amount of alcohol you drink and only take sleeping pills or tranquilisers if your doctor prescribes them along with SIBELIUM.

Galactorrhoea (excessive discharge of milk from the breasts) has been reported in some women on oral contraceptives within the first two months of SIBELIUM treatment.

Hepatic enzyme inducers such as carbamazepine and phenytoin (used in the treatment of epilepsy) may interact with SIBELIUM by increasing its metabolism. An increase in the dosage of SIBELIUM may be required.

SIBELIUM with food, drink and alcohol:

Always take SIBELIUM after a meal whenever possible to avoid stomach irritation. Swallow the tablets whole with water.

Do not drink alcohol while taking SIBELIUM tablets. The combined effect of SIBELIUM tablets and alcohol can make you drowsy.

Pregnancy, Breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking SIBELIUM.

If you are pregnant or think you are, you should not take SIBELIUM.

Do not breastfeed if you are taking SIBELIUM. Consult your doctor in that case.

Driving and using machinery

You may get sleepy with SIBELIUM, especially at the beginning of treatment. Be careful when using machines or driving.

SIBELIUM contains "lactose" (a type of sugar)

If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking SIBELIUM

3. How to take SIBELIUM:

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

Always take SIBELIUM exactly as described in this leaflet or as your doctor, or pharmacist or nurse has have told you. Check with your doctor or, pharmacist or nurse if you are not sure.

Your doctor will tell you how long you need to take SIBELIUM.

Swallow the tablet with a little water.

Never take more than the number of tablets you are supposed to.

If you are taking SIBELIUM, it must be under supervision of your doctor.

If you take SIBELIUM for several months, stay in touch with your doctor.

Starting SIBELIUM treatment in adults:

- For adults aged 18 to 64 years, take 10 mg SIBELIUM every day before going to bed.
- For adults aged 65 years or over, take 5 mg SIBELIUM every day before going to bed.

You may experience some benefit within the first month, but it may take two months before you feel the full effect of SIBELIUM.

Continuing with SIBELIUM in adults:

After one or two months, your doctor will tell you whether you should continue with SIBELIUM.

The dose will be as described below:

Take the same dose as you are used to taking 5 mg or 10 mg SIBELIUM every day before going to bed) for 5 days in a row, and do not take any SIBELIUM for 2 days in a row. Repeat this pattern (5 days with medicine followed by 2 days with no medicine) for the rest of the treatment.

Treatment with SIBELIUM [~~will~~] last**s** at most 6 months. If you stop, but your symptoms come back, you should consult your doctor, who will decide if you should start SIBELIUM again.

Taking SIBELIUM to prevent migraine attacks in children:

- For children aged 6 to 17 years, take 5 mg SIBELIUM every day before going to bed
- In some children, the dose may be increased to 10 mg SIBELIUM every day, depending on the child's body weight

After 3 months, your doctor will tell you whether the child should continue with SIBELIUM. Treatment with SIBELIUM lasts at most 6 months.

If you take more SIBELIUM than you should:

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

Contact your doctor if you have taken too much SIBELIUM. You may experience sleepiness, tiredness agitation or a fast heart beat.

If you forget to take SIBELIUM

If you forget to take SIBELIUM, do not take the missed dose. Wait and take your next dose as usual, then continue your course of SIBELIUM.

Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects:

SIBELIUM can have side effects.

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

Tell your doctor as soon as possible if you notice or suspect any of the following. You may need medical treatment.

- Tingling or numbness in the hands or feet
- Buzzing, hissing, whistling or ringing in the ears (tinnitus)
- Jerky movements and problems such as slowness, muscle stiffness or rigidity and trembling. Twitching or unusual movements of the tongue, mouth, jaw or throat. If you get any of these effects, you may be given an additional medicine.

Frequent side effects:

- Increase in body weight

- Increased appetite
- Itchy, blocked or runny nose
- Feeling low or depressed
- Problems with sleeping or feeling sleepy
- Feeling sick
- Constipation
- Tummy ache or other digestive problems
- Muscle aches
- Pain in the breasts
- Menstrual problems such as irregular periods
- Feeling tired
- Upper abdominal pain

Less frequent side effects:

- Feeling depressed
- Sleep problems
- Lack of interest or emotion (apathy)
- Spasm in the neck that you cannot control, causing the head to twist to one side
- Persistent ringing in the ears (tinnitus)
- Feeling very sleepy with low energy
- Unusual feeling in the skin (such as tingling or a crawling feeling)
- Feeling sluggish
- Feeling restless
- Loss of coordination
- Feeling disorientated
- Heart beat feels fast or uneven (palpitations)
- Blockage of the gut

- Problems with the gut
- Dry mouth
- Excessive sweating
- Muscle spasms
- Muscle twitching
- Menstrual periods that happen less often than normal
- Long or heavy menstrual periods
- Enlarged breasts
- Changes in menstrual cycle (periods)
- Decreased sex drive
- Swelling caused by fluid build up in the body
- Feeling weak
- Swollen hands, ankles or feet
- Allergic reaction (hypersensitivity)
- Difficulty sleeping
- Feeling anxious
- Feeling restless or difficulty sitting still
- Slow movement
- Muscle stiffness and abnormal limb movements
- Slow, jerking or twisting movements that you cannot control
- Muscle tremors, particularly in the arms and hands
- Problems controlling movements of the body or limbs (extrapyramidal disorder)
- Slow movements, with tremor, stiffness and a shuffling walk
- Problems walking
- Feeling sleepy
- Muscle tremors
- Low blood pressure

- Flushing
- Indigestion
- Nausea
- Vomiting
- Severe allergic reaction causing a swollen face, lips, mouth, tongue or throat, which may lead to difficulty swallowing or breathing
- Hives
- Itching
- Skin rash
- Redness of the skin
- Muscle stiffness
- Unexpected production of breast milk

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 "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 SIBELIUM.

Alternatively, you may report side effects experienced with SIBELIUM directly to Janssen Pharmaceutica (see section 'Holder of the Certificate of Registration' for contact details or visit www.janssen.com).

5. How to store :

- Store all medicines out of reach of children.
- Store at or below 25 °C.

- Protect from light and store in a dry place.
- This medicine can be kept for only a limited period
- Do not use SIBELIUM after the date (month and year) printed after "EXP", even if it has been stored properly.
- Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example).
- 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 SIBELIUM contains:

SIBELIUM T 5 mg tablet: Printed carton containing one or more aluminium/aluminium strips of 10 tablets.

SIBELIUM 10 mg tablet: Carton containing one or more blister strips of 7 or 10 tablets each.

What SIBELIUM looks like and contents of the pack

SIBELIUM T 5 mg tablet: White, oblong tablet with the inscription "J-C" on one side and "FL 5" on the other side.

SIBELIUM 10 mg tablet: White, circular, flat, bevel-edged, half-scored tablet with the inscription “JANSSEN” on one side and “FL /10” on the other side.

Holder of certificate of registration:

JANSSEN PHARMACEUTICA (Pty.) Ltd.

(Reg No.: 1980/011122/07)

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This leaflet was revised in:

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Registration numbers:

SIBELIUM T 5 mg tablet: 43/5.7.1/0451

SIBELIUM 10 mg tablet: M/5.7.1/530

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.