

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

SELSUN 2,5 %, suspension

The active substance per 100 g suspension is 2,5 g selenium sulphide.

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

SELSUN 2,5 % is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SELSUN 2,5 % carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SELSUN 2,5 % 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 after 10 days.

What is in this leaflet

1. What SELSUN 2,5 % is and what it is used for
2. What you need to know before you use SELSUN 2,5 %
3. How to use SELSUN 2,5 %
4. Possible side effects

5. How to store SELSUN 2,5 %
6. Contents of the pack and other information

1 What SELSUN 2,5 % is and what it is used for

SELSUN 2,5 % is used as an anti-seborrhoeic agent. You can use it for the treatment of common dandruff and mild and moderately severe cases of seborrhoeic dermatitis (excessive secretion of sebum) of the scalp. It can control chronic seborrhoeic scalp conditions and is also effective in the treatment of ringworm.

2 What you need to know before you use SELSUN 2,5 %

SELSUN 2,5 % is for external use only.

Do not use SELSUN 2,5 %:

- if you are hypersensitive (allergic) to selenium sulphide or any of the other ingredients of SELSUN 2,5 % (listed in section 6).
- Do not apply SELSUN 2,5 % to inflamed or weeping skin.
- Do not allow the product to get into your eyes. If this happens, rinse thoroughly with cold water.

Warnings and precautions

Take special care with SELSUN 2,5 %:

- Gold, silver and other metallic jewellery should be removed before use, since discolouration of the jewellery may be caused.

- Do not leave the shampoo in contact with your hair or skin for more than the recommended time as irritation, burning sensation or blistering of your skin may occur.
- Do not use more often than recommended.

KEEP OUT OF REACH OF CHILDREN.

Rinse SELSUN 2,5 % thoroughly from your hair before dyeing, tinting, or permanent waving the hair. Do not apply SELSUN 2,5 % for a period of two days before or after any of these procedures.

Other medicines and SELSUN 2,5 %

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

Pregnancy and breastfeeding

The safety of SELSUN 2,5 % in pregnancy and breastfeeding has not been established.

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 using this medicine.

Driving and using machines

It is not always possible to predict to what extent SELSUN 2,5 % may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SELSUN 2,5 % affects them.

3 How to use SELSUN 2,5 %

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

Always use SELSUN 2,5 % exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you use SELSUN 2,5 % for dandruff or seborrhoeic dermatitis, the dosage instructions are as follows:

- Shake the bottle before using.
- Massage about 5 to 10 ml of SELSUN 2,5 % suspension into the wet scalp with warm water, until you get a rich, creamy lather.
- Allow lather to remain on the scalp for 2 to 3 minutes.
- Rinse the scalp thoroughly.
- Repeat application and rinse thoroughly.
- After treatment, wash your hands.

Normally, two applications per week for two weeks will be sufficient to treat your condition. After the first two weeks, you can use the SELSUN 2,5 % less frequently – weekly, every 2nd week or even every 3rd to 4th week should be sufficient. Do not use SELSUN 2,5 % more frequently than required to maintain control.

Mentholatum SA (Pty) Ltd
Selsun 2,5 %
2,5 g Selenium sulphide per 100 ml suspension

If you use SELSUN 2,5 % for pityriasis versicolor (ringworm) the dosage

instructions are as follows:

- Shake the bottle well before using.
- Apply SELSUN 2,5 % to the whole body, avoiding contact with your eyes and mucous surfaces. Leave on your body for 10 minutes and then rinse well.
- Repeat the procedure daily for a total of 7 applications.

Do not use more than the required treatments unless the condition does not clear up after 7 treatments or if the infection recur.

If you use more SELSUN 2,5 % than you should

If the product is in contact for the skin for too long, it may cause irritation and dermatitis. It is important to rinse thoroughly after use.

Selenium sulphide is extremely insoluble. If you accidentally swallow the product, you might experience nausea and vomiting. SELSUN 2,5 % could be highly toxic. Symptoms include a garlic odour in the breath, loss of appetite, vomiting and anaemia.

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

To treat accidental oral ingestion of SELSUN 2,5 % the doctor will induce vomiting or empty the stomach by giving a saline purgative (such as sodium

Mentholatum SA (Pty) Ltd
Selsun 2,5 %
2,5 g Selenium sulphide per 100 ml suspension

sulphate 30 g in 250 ml of water), to promote peristalsis. Urinary excretion may be increased by ascorbic acid (Vitamin C) given by mouth.

Further treatment should be symptomatic.

If you forget to use SELSUN 2,5 %

Do not use a double dose to make up for forgotten individual doses.

4 Possible side effects

SELSUN 2,5 % can have side effects.

Not all side effects reported for SELSUN 2,5 % are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using SELSUN 2,5 %, please consult your health care provider for advice.

The application of SELSUN 2,5 % to the skin or scalp can cause irritation or sensitivity, sometimes described as a burning sensation. Blistering can also occur.

Your hair may become more oily following the use of SELSUN 2,5 %.

The skin of the scalp or adjacent skin can become sensitive. If you experience hypersensitivity, stop using the product.

If SELSUN 2,5 % gets into your eyes, the lining of the eyes can become inflamed. Therefore avoid contact with your eyes.

If you apply SELSUN 2,5 % to inflamed skin, the product can be absorbed and cause toxic side effects. SELSUN 2,5 % suspension should not be used when acute inflammation is present.

Mentholatum SA (Pty) Ltd
Selsun 2,5 %
2,5 g Selenium sulphide per 100 ml suspension

Yellow or orange discolouration of grey or white hair may occur following use of SELSUN 2,5 % suspension but can usually be avoided by thorough, careful rinsing of the hair after treatment.

SELSUN 2,5 % suspension should be rinsed (five minutes under cool, running water) from the hair before dyeing, tinting or permanent waving.

When you apply SELSUN 2,5 % suspension to your body for treatment of pityriasis versicolor, take care to avoid contact with the eyes, the genital regions and other mucous surfaces.

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 SELSUN 2,5 %. You may also report side effects directly to <https://www.mentholatum.co.za>

5 How to store SELSUN 2,5 %

Store at or below 25 °C.

Do not use after the expiry date stated on the container.

Mentholatum SA (Pty) Ltd
Selsun 2,5 %
2,5 g Selenium sulphide per 100 ml suspension

Return all unused medicine to your pharmacist.

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

Store all medicines out of reach of children.

6 Content of the pack and other information

What SELSUN 2,5 % contains

The active substance per 100 g suspension is 2,5 g selenium sulphide.

The other ingredients are bentonite, titanium dioxide, glyceryl Monoricinoleate S, citric acid monohydrate, monoethanolamine lauryl sulphate, surfactant Empigen BB, sodium dihydrogen phosphate dehydrate, Bush Boake Allen perfume LC 01618, sodium chloride, sodium hydroxide for pH adjustment and purified water.

What SELSUN 2,5 % looks like and contents of the pack

SELSUN 2,5 % is an orange suspension with a distinctive smell.

SELSUN 2,5 % is presented in plastic bottles of 50 ml and 100 ml.

Holder of Certificate of Registration

Mentholatum South Africa (Pty) Ltd.

1st Floor, Silverberg Terrace

Steenberg Office Park

Silverwood Close

Tokai

Cape Town

7945

Tel No: 021 – 702 0620 / 21

Mentholatum SA (Pty) Ltd
Selsun 2,5 %
2,5 g Selenium sulphide per 100 ml suspension

This leaflet was last revised in

October 2019

Application number

G 1410 (Act 101/1965)

Access to the corresponding Professional Information

The PI can be found online under Mentholatum SA's website:

<https://www.mentholatum.co.za/product-information/>.