PSORIN® SCALP GEL

PATIENT INFORMATION LEAFLET

What you should know about Psorin Scalp Gel.

Please read this leaflet carefully before you start to use your treatment. This leaflet does not contain complete information about your treatment. If you have any questions or are not sure about anything ask your doctor or pharmacist (chemist). Keep this leaflet until you have finished all your treatment. You may want to read it again. The information provided in this leaflet is in accordance with the product licence.

The name of your medicine is Psorin Scalp Gel.

Quantitative Formula:

Psorin Scalp Gel contains Dithranol BP (0.25% w/w) and Salicylic Acid Ph.Eur. (1.6% w/w). Other ingredients are white soft paraffin, light liquid paraffin, methyl salicylate. Psorin Scalp Gel comes in 50g tubes.

Indications:

For topical treatment of psoriasis of the scalp.

Manufactured by:

Pharmaserve Ltd, Clifton Technology Park, Wynne Avenue, Swinton, Manchester M27 8FF.

PL Holder:

Boston Healthcare Ltd., Unit 6, Navigation Court, Calder Park, Wakefield WF2 7BJ.

What does Psorin Scalp Gel do?

Psorin Scalp Gel is applied to the scalp for the treatment of psoriasis. It should help to rid the skin on the scalp of visible signs of psoriasis, restoring a more normal skin appearance.

Before using your treatment

- Have you been told or do you think you may be sensitive to dithranol, salicylic acid or any of the other ingredients?
- Do you suffer from acute or pustular psoriasis or unstable psoriasis where the skin is hot to touch, itchy and gets worse in the sun?
- · Have you used potent topical steroids in the last two weeks?
- · Are you pregnant or breast feeding?
- · Has any redness resulted from the 24 hour skin test?

If the answer is **yes** to any of these questions tell your doctor or pharmacist.

Using your treatment

- Psorin Scalp Gel should be patch tested before treatment begins. Apply a small quantity to an area of the scalp affected by psoriasis, leave for 20 minutes then wash off with a neutral or slightly acidic shampoo. You should wait for at least 24 hours to see what happens. If there is no major change you can begin treating your psoriasis. You may experience a feeling of warmth or burning. If the burning is severe you should not use Psorin Scalp Gel and consult your doctor or pharmacist.
- Psorin Scalp Gel should be massaged into areas of the scalp affected by psoriasis. Avoid spreading the gel to healthy skin. Wash the hands after use or use disposable gloves. Leave the application for 10 to 20 minutes then remove with a suitable shampoo.
- For best results you should do this every second day or as recommended by the doctor or pharmacist.

- The treatment may induce a feeling of warmth. If there is a prolonged or severe burning sensation the Scalp Gel should be removed after 5-10 minutes. Normally this sensation resolves within 3-4 days and you may then follow the instructions above. If the burning does not resolve you should consult your doctor.
- Psorin Scalp Gel contains dithranol which can cause staining of the skin, hair and clothing. Staining of healthy skin will be more marked. This will clear when treatment is stopped.
- Avoid contact with the eyes and sensitive skin such as the face, skin folds and genitals.

Warnings:

Effective treatment may induce a feeling of warmth. If there is a prolonged or severe burning sensation the contact time should be reduced. Normally this sensation resolves within 3-4 days and the full treatment regime can be resumed. In extreme cases it may be necessary to stop treatment. Dithranol causes staining of the skin, hair and clothing. Staining of healthy skin will be more marked and will resolve after cessation treatment. Avoid contact with eyes, mouth and nose.

After using your treatment

Stop applying Psorin Scalp Gel if any irritation of the skin occurs and consult your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

Expiry date warning

Do not apply this gel if it is after the expiry date on the label.

Storing your Psorin Scalp Gel

- Do not store above 25°C. Store in the original container in order to protect from light.
- Keep all medicines in a safe place where children cannot reach or see them.

More information:

REMEMBER: This gel has been recommended just for you. Never give it to others. It may not be suitable for them even if their symptoms seem the same as yours.

You may wish to contact: The Psoriasis Association, 7 Milton Street, Northampton NN2 7JG.

Boston Healthcare Ltd., 6 Navigation Court, Calder Park, Wakefield WF2 7BJ.

