Package leaflet: Information for the user

Oilatum® Junior Flare-Up Bath Additive

light liquid paraffin52.5% w/w, benzalkonium chloride 6.0% w/w, triclosan 2.0% w/w

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Oilatum Junior Flare-Up Bath Additive is and what it is used for
- 2. What you need to know before you take Oilatum Junior Flare-Up Bath Additive
- 3. How to use Oilatum Junior Flare-Up Bath Additive
- 4. Possible side effects
- 5. How to store Oilatum Junior Flare-Up Bath Additive
- 6. Contents of the pack and other information

1. What Oilatum Junior Flare-Up Bath Additive is and what it is used for

Oilatum Junior Flare-Up Bath Additive contains the emollient light liquid paraffin 52.5% w/w and the antiseptics benzalkonium chloride 6.0% w/w and triclosan 2.0% w/w. It also contains acetylated wool alcohols, isopropyl palmitate, oleyl alcohol and macrogol lauryl ether.

Oilatum Junior Flare-Up Bath Additive is for treating eczemas when they flare-up and are at risk of becoming infected. Using it early can help to reduce the duration and severity of the flare-up. You should continue to use the product until the flare-up subsides.

2. What you need to know before you take Oilatum Junior Flare-Up Bath Additive Additive

Oilatum Junior Flare-Up Bath Additive may not be right for some people. If the user is known to be allergic to any of the ingredients of this medicine (listed in section 6) then the product should not be used.

Oilatum Junior Flare-Up Bath Additive is not recommended for babies younger than 6 months.

Avoid contact of the undiluted product with the eyes.

The preparation should not be applied directly to the skin.

Take care to avoid slipping in the bath.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it

Oilatum Junior Flare-Up Bath Additive contains acetylated wool alcohol

May cause local skin reactions (e.g. contact dermatitis).

3. How to use Oilatum Junior Flare-Up Bath Additive

Oilatum Junior Flare-Up Bath Additive is an effective cleanser and should not be used with soap. You should not use Oilatum Junior Flare-Up Bath Additive neat (undiluted) on your skin, it should always be diluted with water.

Adults and Children: In an eight inch bath add 2 capfuls. In a four inch bath add 1 capful.

Infants: Add 1ml (just sufficient to cover the bottom of the cap) and mix well with water.

Soak for 10 - 15 minutes, gently pat the skin dry with a clean towel. Use once daily.

TAKE CARE TO AVOID SLIPPING IN THE BATH

The undiluted product should not be allowed to come into contact with the eyes. If the undiluted product accidentally comes into contact with the eyes, reddening may occur.

You should wash the eyes thoroughly with clean water for 15 minutes. If there is persistent irritation, you should ask your pharmacist or doctor for advice taking the bottle with you.

The product is only intended for use on the skin when diluted with water. It should not be taken internally. If the undiluted product is accidentally swallowed; drink 1 to 2 glasses of milk or water and ask your doctor for advice taking this bottle with you.

The product is only intended for use on the skin when diluted with water. It should not be taken internally. If the undiluted product is accidentally swallowed; drink 1 to 2 glasses of milk or water and ask your doctor for advice taking this bottle with you. If a large quantity of the undiluted product is swallowed, you should contact your hospital casualty department for advice.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Not known (frequency cannot be estimated from the available data):

• Hypersensitivity reactions, and local skin reactions (e.g. contact dermatitis with triclosan).

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:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Oilatum Junior Flare-Up Bath Additive

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after "EXP". The expiry date refers to the last day of that month.

There are no special storage requirements.

6. Contents of the pack and other information

Oilatum Junior Flare-Up Bath Additive is supplied in bottles containing 150ml bath additive and 300ml bath additive. Not all pack sizes may be marketed.

The active substances of *Oilatum Junior Flare-Up Bath Additive are* Light liquid paraffin 52.5 %w/w, Benzalkonium chloride 6.0 %w/w, Triclosan 2.0 %w/w. The other ingredients are Acetylated wool alcohols, Isopropyl palmitate, Oleyl alcohol and Macrogol lauryl ether.

Oilatum Junior Flare-Up Bath Additive is a clear pale yellow oily solution.

Product Authorisation Holder:

Clonmel Healthcare Limited, Waterford Rd, Clonmel, Co. Tipperary, Ireland.

Manufacturer:

Clonmel Healthcare Limited, Waterford Rd, Clonmel, Co. Tipperary, Ireland.

This leaflet was last revised in April 2021