



20/01/2023

Our FSCA Ref: NC/D707
Our FSN Ref: NC/D707

Field Safety Notice

Epimax Ointment, Epimax Paraffin Free Ointment and Epimax Original Cream

Not batch specific

Advisory Notice to Healthcare Professionals

MHRA Ref. 2022/001/012/601/028

For the attention of Healthcare Professionals,

Aspire Pharma Limited is writing to notify you that we are in the process of updating our product labelling/packaging, due to having received a localised cluster of reports in Scotland, concerning eye-related injuries sustained by patients following the use of these products from the Epimax range on or around the skin of the eyes. All three products contain cetostearyl alcohol, a known potential skin sensitiser, which is postulated to be the cause of the eye irritation or injuries.

Details of affected medical devices

Legal Manufacturer	Product Description	Batch Number	UK Incident Rate	Scotland Incident Rate
Aspire Pharma Limited	Epimax Ointment	Not specific	0.006%	0.039%
Aspire Pharma Limited	Epimax Paraffin Free Ointment	Not specific	0.003%	0.000%
Aspire Pharma Limited	Epimax Original Cream	Not specific	0.000%	0.002%

The Epimax range are Class I Medical Devices indicated as emollients/ moisturisers for use in eczema, psoriasis and other dry skin conditions. They are suitable for all ages and for use on the skin, all over the body, as frequently as required. Epimax Original Cream can be used as a soap substitute when washing in the bath or shower. Epimax Ointment and Epimax Paraffin Free Ointment can be used as a soap substitute or a bath additive. All products are topical only products and warnings to avoid contact with the eyes are clearly present on the labels.

Aspire Pharma will update the product labelling to make it clear that the product can be used as a **body wash**, rather than a **soap substitute** which could be used around the eyes. We will also include advice to rinse the eyes and seek medical advice if the product does accidentally come into contact with the eyes.

Further general information regarding Epimax Ointment, Epimax Paraffin Free Ointment and Epimax Original Cream, including a full list of ingredients, can be accessed at www.epimax.co.uk. The latest approved artwork (one pack size per product) is included in this Field Safety Notice.

Please ensure that patients are aware to avoid contact of these products with their eyes.

Please maintain awareness on this notice and resulting action for an appropriate period. Should you be made aware of any medical device incidents, please promptly report them to Aspire Pharma Limited, your distributor and the MHRA, as this provides important feedback.

Aspire Pharma Limited
4 Rotherbrook Court Bedford Road Petersfield Hampshire GU32 3QG
T: +44 01730 231148 W: www.aspirepharma.co.uk E: info@aspirepharma.co.uk



Aspire Pharma Limited is in the process of launching Epimax Eyelid Ointment, which is formulated specifically for use around the eyes, and is currently applying to the Drug Tariff for reimbursement.

Aspire Pharma Limited are committed to improving our product packaging to deliver safe and high-quality products. We apologise for any inconvenience this may have caused and thank you for your cooperation. If you require any further information, please do not hesitate to contact our Medical Information Team.

Medical Information Team

Email: medinfo@aspirepharma.co.uk

Tel.: 01730 231148

Yours sincerely

A handwritten signature in blue ink that reads "Jon May".

Jon May

General Manager

Aspire Pharma Limited
4 Rotherbrook Court Bedford Road Petersfield Hampshire GU32 3QG
T: +44 01730 231148 W: www.aspirepharma.co.uk E: info@aspirepharma.co.uk

EPIMAX[®] Ointment
can be used all over the body and is suitable for all ages.

Directions: Apply to skin as frequently as required, smoothing gently into the affected areas in the direction of hair growth. Can also be used as a body wash or bath additive. **As a bath additive:** melt about 4g (the size of a £2 coin) in hot water and add to the bath. Care should be taken as this can make the bath slippery.

Precautions: For external use only. Avoid contact with the eyes. In the event of accidental contact rinse well with water. Do not use if allergic to any of the ingredients. This product contains cetostearyl alcohol, which may cause local skin reactions. Seek medical advice before use if the skin is broken, infected, or bleeding, or after use if any undesirable effects are experienced, if accidentally swallowed, or if the product comes into contact with the eyes.

Ingredients: Liquid paraffin 40% w/w, cetomacrogol emulsifying wax (contains cetostearyl alcohol and macrogol cetostearyl ether), yellow soft paraffin 30% w/w.

Store below 25°C. Do not freeze. Do not use after the expiry date. Use within 3 months of initial opening.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

 **Fire hazard. Do not smoke or go near naked flames; clothing & bedding with this product dried on them can catch fire easily.**

Text revised: 01/2023 1010455-14.2 www.epimax.co.uk

500ge

EPimax[®]

ointment

Liquid paraffin,
Yellow soft paraffin

**For daily use in eczema, psoriasis
and dry skin conditions**

Free from fragrances, SLS,
parabens and lanolin

**Lasting protection
for intensive relief,
day and night**










060209 732503

Aspire Pharma Ltd
4, Rotherbrook Court
Bedford Rd, Petersfield
Hants, GU32 3QG, UK



EPIMAX[®] Paraffin-Free Ointment
can be used all over the body and is suitable for all ages.

Directions: Apply to skin as frequently as required, smoothing gently into the affected areas in the direction of hair growth. Can also be used as a body wash or bath additive. **As a bath additive:** melt about 4g (the size of a £2 coin) in hot water and add to the bath. Care should be taken as this can make the bath slippery.

Precautions: For external use only. Avoid contact with the eyes. In the event of accidental contact rinse well with water. Do not use if allergic to any of the ingredients. This product contains cetostearyl alcohol, which may cause local skin reactions. Seek medical advice before use if the skin is broken, infected, or bleeding, or after use if any undesirable effects are experienced, if accidentally swallowed, or if the product comes into contact with the eyes.

Ingredients: Polyoxyethylene hydrogenated castor oil 38% w/w, macrogol cetostearyl ether, medium chain triglycerides, polyoxypropylene stearyl ether, cetostearyl alcohol, hydrogenated castor oil, D&C Yellow/Red.

Store below 25°C. Do not freeze. Do not use after the expiry date. Use within 3 months of initial opening.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

 **Fire hazard. Do not smoke or go near naked flames; clothing & bedding with this product dried on them can catch fire easily.**

Text revised: 02/2023 1010477-14.2 www.epimax.co.uk

500ge


EPimax[®]

paraffin-free ointment


For daily use in eczema, psoriasis
and dry skin conditions

Free from fragrances, SLS,
parabens and lanolin

**Lasting protection
for intensive relief,
day and night**










060209 732480

Aspire Pharma Ltd
4, Rotherbrook Court
Bedford Rd, Petersfield
Hants, GU32 3QG, UK



500g^e

EPimax[®]

original cream

white soft paraffin,
liquid paraffin

For light
hydration
and gentle
relief

For daily use in eczema,
psoriasis and dry skin conditions

Free from fragrances, SLS,
parabens and lanolin

EPIMAX[®]

Original Cream
can be used all over the body
and is suitable for all ages.

Directions: Apply to skin as frequently as required,
smoothing gently into the affected areas in the direction
of hair growth. Can also be used as a body wash.

Precautions: For external use only. Avoid contact with the eyes, in the
event of accidental contact rinse well with water. Do not use if allergic
to any of the ingredients. This product contains cetostearyl alcohol and
phenoxyethanol, which may cause local skin reactions. Seek medical
advice before use if the skin is broken, infected, or bleeding; or after
use if any undesirable effects are experienced, if accidentally
swallowed, or if the product comes into contact with the eyes.

Ingredients: White soft paraffin 15% w/w, cetostearyl alcohol,
liquid paraffin 6% w/w, polysorbate 60, phenoxyethanol and water.
Store below 25°C. Do not freeze. Do not use after the expiry date.
Use within 3 months of initial opening.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN



**Fire hazard. Do not smoke or go near naked
flames; clothing & bedding with this
product dried on them can catch fire easily.**



Aspire Pharma Ltd
4, Rotherbrook Court
Bedford Rd, Petersfield, Hants
GU32 3QG, United Kingdom



Text revised: 01/2023 1010452-L4.2



www.epimax.co.uk



5 060209 732459

LOT



Aspire Pharma Limited

4 Rotherbrook Court Bedford Road Petersfield Hampshire GU32 3QG

T: +44 01730 231148 W: www.aspirepharma.co.uk E: info@aspirepharma.co.uk