

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S0

### VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM

CATEGORY D COMPLEMENTARY PRODUCT

DISCIPLINE: Discipline Specific Traditional 33.7 – Combination Product

This unregistered product has not been evaluated by the South African Health Product Regulatory Authority for its safety, quality or intended use.

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

- **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM** is available without a doctor's prescription, for you to treat a mild condition. Nevertheless you still need to use **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM** carefully.
- Keep this leaflet. You may need to read it again.
- Do not share **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor or health care professional if your symptoms worsen or do not improve after a few days.

#### What is in this leaflet

1. What **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM** is and what it is used for.
2. What you need to know before you take/ use **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM**.
3. How to take /use **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM**.
4. Possible side effects.
5. How to store **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM**.
6. Contents of the pack and other information.

#### 1 What **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM** is and what it is used for:

Each application provides:

Maize Starch, Honey, Zinc Oxide, Vitis Vinifera (Grape Seed) Oil, Petrolatum, Paraffinum Liquidum (Mineral Oil), Beeswax (Cera Alba), Glycine Soja (Soybean) Oil, Cocos Nucifera (Coconut) Oil, Lanolin, Dimethicone, Butyrospermum Parkii (Shea) Butter, Tocopherol, Simmondsia Chinensis (Jojoba) Alcohol, Calendula Officinalis Flower Extract, Potassium Jojobate, Jojoba Alcohol, Propanediol, Butylated Hydroxytoluene (BHT).

**VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM** is indicated as a general supplement where a deficiency of any of the ingredients exists.

#### 2 What you need to know before you take/ use **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM**:

Do not use **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM** if you are hypersensitive (allergic) to any of the ingredients.

#### Warnings and precautions:

Discontinue the use of this product where there is sensitivity towards any of the ingredients. Typically, beeswax may cause allergic contact dermatitis. In most cases, this reaction is likely caused by the propolis component of beeswax.

#### Other products and **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM**:

None.

#### Take special care:

Typically, beeswax may cause allergic contact dermatitis. In most cases, this reaction is likely caused by the propolis component of beeswax.

#### 3 How to take /use **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM**.

Apply liberally to the affected area, with each nappy change or as needed. For external use only.

#### If you take more than you should:

No known symptoms.

#### 4 Possible side effects:

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

**If any of the following happens, stop taking and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

If you may have had a serious allergic reaction to **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM**. You may need urgent medical attention or hospitalisation.

#### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or health care professional. This includes any possible side effects not listed in this leaflet. 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 **VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM**.

#### **5 How to store VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM**

Store at or below 25° C. Protect from light and moisture. Keep out of reach of children.

#### **6 Contents of the pack and other information:**

##### **What VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM contains:**

Maize Starch, Honey, Zinc Oxide, Vitis Vinifera (Grape Seed) Oil, Petrolatum, Paraffinum Liquidum (Mineral Oil), Beeswax (Cera Alba), Glycine Soja (Soybean) Oil, Cocos Nucifera (Coconut) Oil, Lanolin, Dimethicone, Butyrospermum Parkii (Shea) Butter, Tocopherol, Simmondsia Chinensis (Jojoba) Alcohol, Calendula Officinalis Flower Extract, Potassium Jojobate, Jojoba Alcohol, Propanediol, Butylated Hydroxytoluene (BHT).

The applicable part of calendula is the flower. The flower petals contain coumarins, esculetin, scopoletin, umbelliferon (7-hydroxycoumarin), tocopherols, alpha-tocopherolquinone, and calenduloside B. At least eight bioactive triterpene diol monoesters have been identified in the extracts of dried calendula flowers. Calendula also contains minerals, carbohydrates, lipids, phenolic acids, flavonoids, tannins, coumarins, sterols and steroids, monoterpenes, sesquiterpenes, triterpenes, tocopherols, quinones, amino acids, and resins. **Wound healing effects:** Calendula is used for wound healing due to potential anti-inflammatory effects. The faradiol monoester is believed to play an important role in the anti-inflammatory activity. Some evidence suggests the water-soluble flavonoids might also be responsible for the wound-healing effects.

Clinical research shows that applying 47% zinc oxide paste to affected areas for 5 days can improve the healing of diaper rash.

**Wound-healing effects:** For aiding in wound healing, topical zinc might enhance re-epithelialization and collagen synthesis, decrease inflammation, and inhibit bacterial growth.

Beeswax is a complex mixture of hydrocarbons, free fatty acids, esters of fatty acids, fatty alcohols, and other substances. The exact composition of beeswax varies between different families and breeds of bees. Preliminary clinical research shows that topical use of a mixture of honey, olive oil, and beeswax four times daily for 7 days reduces symptoms of diaper rash by more than 75%.

##### **What VITAFEN BABY – NAPPY RASH AND ECZEMA CREAM look like and contents of the pack:**

Carton with printed LDPE tube containing 50 g of white, thick, odourless cream.

##### **Holder of the certificate of registration:**

Pharmafen (Pty) Ltd  
Pretoria  
South Africa  
info@pharmafen.co.za  
www.pharmafen.co.za

##### **This leaflet was last revised in:**

August 2023

##### **Registration number:**

This product has not been evaluated by the South African Health Products Regulatory Authority. This product is not intended to diagnose, treat, cure or prevent any disease

##### **Access to the corresponding Professional Information**

Can be obtained on the Pharmafen website.

## PASIËNT INLIGTINGSPAMFLET

### SKEDULERINGSSTATUS:

S0

### VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM

#### KATEGORIE D AANVULLENDE GENEESKUNDE

DISSCIPLINE: Dissiplinespesifieke Tradisioneel 33.7 – Kombinasieprodukt

Hierdie ongeregistreerde produk is nie deur die Suid-Afrikaanse Gesondheidsprodukt Regulerende Owerheid (SAHPRA) geëvalueer vir sy veiligheid, kwaliteit of beoogde gebruik nie.

#### Lees die hele pamflet noukeurig deur, want dit bevat belangrike inligting vir jou

- **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** is beskikbaar sonder 'n dokter se voorskrif, vir jou om 'n luierruutslag te behandel. Nietemin moet jy steeds **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM versigtig** gebruik om die beste resultate daaruit te kry.
- Bewaar hierdie pamflet vir toekomstige gebruik.
- Moenie **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** met enige ander persoon deel nie .
- Vra jou apteker of gesondheidsdeskundige indien jy meer inligting of advies benodig.
- U moet u gesondheidsdeskundige spreek indien die simptome vererger of nie na 'n paar dae verbeter nie.

#### Wat is in hierdie pamflet

1. Wat **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM neem/gebruik** .
3. **HOE OM VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** te neem/gebruik .
4. Moontlike nuwe-effekte.
5. Hoe om **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** te bêre .
6. Inhoud van die pakkie en ander inligting.

#### 1 Wat **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** is en waarvoor dit gebruik word:

Elke aanwending bevat:

Mieliestysel, heuning, sinkoksied, Vitis Vinifera (druiwepit) olie, petrolatum, paraffinum liquidum (minerale olie), byewas (Cera Alba), glisien Soja (soja) olie, Cocos Nucifera (klapper) olie, lanoliën, dimetikoon, Butospermium Parkii (Shea) Botter, Tocopherol, Simmondsia Chinensis (Jojoba) Alkohol, Calendula Officinalis Blom ekstrakt, Kalium Jojobaat, Jojoba Alkohol, Propandiol, Butylated Hydroxytoluene (BHT).

**VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** word as 'n algemene aanvulling aangedui waar 'n tekort aan enige van die bestanddele bestaan.

#### 2 Wat jy moet weet voor jy **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** neem/gebruik :

Moenie **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** gebruik nie indien jy hipersensitief (allergies) is vir enige van die bestanddele nie.

#### Waarskuwings en voorsorgmaatreëls:

Staak die gebruik van hierdie produk waar daar sensitiwiteit vir enige van die bestanddele is. Topikaal kan byewas allergiese kontakdermatitis veroorsaak. In die meeste gevalle word hierdie reaksie waarskynlik veroorsaak deur die propolis-komponent van byewas.

#### Ander produk en **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** :

Geen.

#### Neem spesiale sorg:

Topikaal kan byewas allergiese kontakdermatitis veroorsaak. In die meeste gevalle word hierdie reaksie waarskynlik veroorsaak deur die propolis-komponent van byewas.

#### 3 Hoe om **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** te neem/gebruik .

Wend midelik aan op die geaffekteerde area, met elke doekwisseling of soos nodig. Slegs vir eksterne gebruik.

#### Indien meer aangewend word indien benodig:

Geen bekende simptome nie.

#### 4 Moontlike nuwe-effekte:

Nie alle nuwe-effekte wat vir hierdie produk gerapporteer word, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige nadelige effekte ervaar terwyl u hierdie produk gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsdeskundige vir advies.

**As enige van die volgende gebeur, hou op om aan te wend en kontak jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:**

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal;
- uitslag of jeuk;
- flou word.

As die baba voorheen 'n ernstige allergiese reaksie op **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** gehad het, mag dringende mediese aandag of hospitalisasie dalk benodig word..

#### Rapportering van nuwe-effekte

As nuwe-effekte ervaar word, kontak jou dokter of apteker of gesondheidsdeskundige. Dit sluit enige moontlike nuwe-effekte in wat nie in hierdie pamflet gelys word nie. Nuwe-effekte kan ook nuwe-effekte aan SAHPRA gerapporteer word via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan jy help om meer inligting te verskaf oor die veiligheid van **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM**.

#### 5 Hoe om **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** te bêre

Berg teen of onder 25° C. Beskerm teen lig en vog. Hou buite bereik van kinders.

#### 6 Inhoud van die pakkie en ander inligting:

**Wat **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** bevat:**

Mieliestysel, heuning, sinkoksied, Vitis Vinifera (druiwepit) olie, petrolatum, paraffinum liquidum (minerale olie), byewas (Cera Alba), glisien Soja (soja) olie, Cocos Nucifera (klapper) olie, lanoliën, dimetikoon, Butospermium Parkii (Shea) Botter, Tocopherol, Simmondsia Chinensis (Jojoba) Alkohol, Calendula Officinalis Blom ekstrak, Kalium Jojobaat, Jojoba Alkohol, Propandiol, Butylated Hydroxytoluene (BHT).

Die toepaslike deel van kalendula is die blom. Die blomblare bevat kumariene, eskuletien, skopoletien, umbelliferon (7-hidroksikumarien), tokoferole, alfa-tokoferolkinoon en kalendulosied B. Ten minste agt bioaktiewe triterpendiol mono-esters is in die ekstrakte van gedroogde gousblomblomme geïdentifiseer. Calendula bevat ook minerale, koolhidrate, lipiede, fenoliese sure, flavonoïede, tanniene, kumariene, sterole en sterioïede, monoterpene, seskviterpene, triterpene, tokoferole, kinone, aminosure en harse. **Wondgenesingseffekte:** Calendula word gebruik vir wondgenesing as gevolg van potensiële anti-inflammatoriese effekte. Daar word geglo dat die faradiol monoëster 'n belangrike rol speel in die anti-inflammatoriese aktiwiteit. Sommige bewyse dui daarop dat die wateroplosbare flavonoïede ook verantwoordelik kan wees vir die wondgenesende effekte.

Kliniese navorsing toon dat die toediening van 47% sinkoksiedpasta vir 5 dae op geaffekteerde areas die genesing van luierslag kan verbeter. **Wondgenesende effekte:** Om te help met wondgenesing, kan sink her-epiteliasering en kollageensintese verbeter, inflammasie verminder en bakteriese groei inhibeer.

Byewas is 'n komplekse mengsel van koolwaterstowwe, vrye vetsure, esters van vetsure, vetalkohole en ander stowwe. Die presiese samestelling van byewas verskil tussen verskillende families en rasse van bye. Voorlopige kliniese navorsing toon dat die gebruik van 'n mengsel van heuning, olyfolie en byewas vier keer per dag vir 7 dae die simptome van luierslag met meer as 75% verminder.

**Wat **VITAFEN BABA – LUIERUITSLAG EN EKSEEM ROOM** lyk en inhoud van die pakkie:**

Karton met gedrukte LDPE-buis wat 50 g wit, dik, reuklose room bevat.

#### Houer van die registrasiesertifikaat:

Pharmafen (Edms.) Bpk  
Pretoria  
Suid-Afrika  
info@pharmafen.co.za  
www.pharmafen.co.za

#### Hierdie pamflet is laas hersien in:

Augustus 2023

#### Registrasienommer:

Hierdie produk is nie deur die Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte (SAHPRA) geëvalueer nie. Hierdie produk is nie bedoel om enige siekte te diagnoseer, te behandel, te genees of te voorkom nie.

#### Toegang tot die ooreenstemmende professionele inligting

Kan verkry word op die Pharmafen webwerf.