

Mom & Baby

DENTAL MELTS (TABLETS)

PATIENT INFORMATION LEAFLET



SCHEDULING STATUS Not scheduled

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Dental Melts (Tablets)

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

Dental Melts are available without a doctor's prescription for the relief of minor conditions. Nevertheless you still need to use Dental Melts carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Dental Melts with any other person.
- Ask your pharmacist or healthcare practitioner if you need more information or advice.
- You must see a healthcare practitioner if your symptoms worsen or do not improve.

1. WHAT DENTAL MELTS CONTAINS

The active ingredients in Dental Melts are *Aconitum napellus* 5CH, *Bryonia cretica* 5CH, *Calcium carbonicum* 5CH, *Calcium fluorium* 5CH, *Calcium phosphoricum* 5CH, *Delphinium staphisagria* (*Staphisagria*) 9CH, *Ferrum phosphoricum* 5CH, *Matricaria rectata* (Chamomilla) 5CH, *Silicea* 5CH, *Strychnos ignatia* (Ignatia) 9CH. The other ingredients are lactose monohydrate, magnesium stearate and sodium starch glycolate.

Contains sugar (lactose 47 mg).

2. WHAT DENTAL MELTS ARE USED FOR

Dental Melts are homeopathically used to help ease teething in babies and children.

3. BEFORE YOU TAKE DENTAL MELTS

Do not take Dental Melts

- If you are hypersensitive (allergic) or intolerant to any of the active ingredients or other ingredients in Dental Melts.

Take special care with Dental Melts:

- If you experience an allergic reaction after taking Dental Melts, discontinue use and consult your healthcare practitioner.
- If you want to substitute existing medical treatment, please consult your doctor or healthcare practitioner before doing so.

Taking Dental Melts with food and drink

Dental Melts should not be taken within 15 minutes of a meal, strong coffee, chocolate, camphor or aromatic substances as these may reduce the efficacy of the homeopathic components.

Pregnancy and breastfeeding

Homeopathic medicines have traditionally been safely used during pregnancy and breastfeeding. It is recommended that if you are pregnant or breastfeeding, that you consult your healthcare practitioner for advice before taking any medicine.

Driving and using machinery

Dental Melts do not interfere with your ability to drive or use machinery.

Important information about some of the ingredients

Dental Melts contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take Dental Melts. Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus.

Using other medicines with Dental Melts

Always tell your healthcare practitioner if you are taking other medicines. (This includes complementary or traditional medicines.) Dental Melts are not known to interact with other medicines.

4. HOW TO TAKE DENTAL MELTS

Do not share medicines prescribed for you with any other person. Always check with your pharmacist or healthcare practitioner if you are unsure how to take this medicine.

The tablets should be dissolved in the mouth, ideally under the tongue. For babies, the tablets should be dissolved in a little water (one teaspoon) and given as a liquid to avoid any risk of the baby choking. The mouth should be free of other strong tastes (e.g. toothpaste, peppermint, etc.) when taking the medicine. As absorption takes place through the mucous membrane of the mouth, it is desirable to hold the medicine in the mouth for a short time.

The normal dosage is:

Babies: 1 Tablet dissolved in the mouth or in a little water every 30 minutes for 4-5 doses. Thereafter 3-4 times daily.

Children: 1-2 Tablets dissolved in the mouth 3 times daily 30 minutes before meals.

Treatment may be continued for as long as necessary and may be stopped at any time when symptoms are no longer present or when no longer necessary.

If you take more Dental Melts than you should

There are no known symptoms of overdose. If a side effect is experienced following an overdose, consult your healthcare practitioner or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of Dental Melts

Do not take a double dose to make up for a missed dose.

5. POSSIBLE SIDE EFFECTS

There are no known side effects for Dental Melts. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare practitioner or pharmacist for advice.

6. STORING AND DISPOSING OF DENTAL MELTS

Store at or below 25°C in a cool, dry place protected from light and moisture. Keep the container tightly closed. Do not store in a bathroom. **Store all medicines out of the reach of children.** Return all un-used medicines to your pharmacist.

7. PRESENTATION OF DENTAL MELTS

Dental Melts are available as 50 tablets packed in an amber glass bottle with a white HDPE screw-on cap.

8. IDENTIFICATION

Dental Melts are small, white, round, bi-convex tablets with a lactose taste.

9. REFERENCE NUMBER

U505 (Act 101/1965)

10. NAME AND ADDRESS OF THE APPLICANT

CoMED Health (Pty) Ltd., 313 Kuit Street, Waltloo, Pretoria, 0184.
www.comedhealth.co.za (See also www.natura.co.za). Tel: 012 813 9400.

11. DATE OF PUBLICATION

June 2018

12. COMPLEMENTARY MEDICINE

Homeopathic medicine

Disclaimer: This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.



Mamma & Baba

DENTAL MELTS (TABLETTE)

PASIËNT INLIGTINGSBLAD



SKEDULERING STATUS Nie geskeduleer nie.

HANDELSNAAM, STERKTE EN DOSEERVORM

Dental Melts (Tablette)

Lees hierdie blaadjie sorgvuldig deur want dit bevat belangrike inligting vir jou

Dental Melts is beskikbaar sonder 'n dokter se voorskryf vir die verligting van geringe toestande. Tog moet Dental Melts noukeurig gebruik word om die beste resultate daaruit te kry.

- Hou hierdie blaadjie veilig in geval jy dit in die toekoms weer moet lees.
- Moet nie Dental Melts met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn as jy meer inligting of advies benodig.
- Jy moet 'n gesondheidsorgpraktisyn sien as jou simptome vererger of nie verbeter nie.

1. WAT DENTAL MELTS BEVAT

Die aktiewe bestanddele in Dental Melts is *Aconitum napellus* 5CH, *Bryonia cretica* 5CH, *Calcium carbonicum* 5CH, *Calcium fluorium* 5CH, *Calcium phosphoricum* 5CH, *Delphinium staphisagria* (*Staphisagria*) 9CH, *Ferrum phosphoricum* 5CH, *Matricaria recutita* (*Chamomilla*) 5CH, *Silicea* 5CH, *Strychnos ignatia* (*Ignatia*) 9CH. Die ander bestanddele is laktose monohidraat, magnesium stearaat en natrium styselglukolaat.

Betvat suiker (laktose 47 mg)

2. WAARVOOR DENTAL MELTS GEBRUIK WORD

Dental Melts word homeopaties gebruik om tandekry te vergemaklik.

3. VOORDAT JY DENTAL MELTS GEBRUIK

Moet nie Dental Melts neem as

- Jy hipersensitief (allergies) of onverdraagsaam is teenoor enige van die aktiewe bestanddele of ander bestanddele in Dental Melts nie.

Wees veral versigtig met Dental Melts:

- Indien jy 'n allergiese reaksie ervaar nadat jy Dental Melts geneem het, stop dadelik die gebruik daarvan en raadpleeg jou gesondheidsorgpraktisyn.
- As jy bestaande mediese behandeling wil vervang, raadpleeg jou dokter of gesondheidsorgpraktisyn voordat jy dit doen.

Gebruik van Dental Melts saam met voedsel en vloeistowwe

Moet nie Dental Melts binne 15 minute neem van 'n ete, sterk koffie, sjokolade, kamfer of aromatiese stowwe nie, aangesien dit die effektiwiteit van die homeopatiese komponente kan verminder.

Swangerskap en borsvoeding

Homeopatiese medisyne is tradisioneel veilig gebruik tydens swangerskap en borsvoeding. Dit word egter aanbeveel dat as jy swanger is of jou baba borsvoed, dat jy jou gesondheidsorgpraktisyn raadpleeg vir advies voordat jy enige medisyne gebruik.

Die gebruik en bestuur van masjinerie

Die gebruik van Dental Melts beïnvloed nie die mens se vermoë om masjinerie te bestuur en veilig te gebruik nie.

Belangrike inligting oor sommige van die bestanddele

Dental Melts bevat laktose. Pasiënte met die seldsame oererlike toestande van laktose of galaktose-onverdraagsaamheid moet nie Dental Melts neem nie. Laktose kan 'n invloed hê op die beheer van jou bloedsuiker as jy diabetes mellitus het.

Gebruik van ander medisyne saam met Dental Melts

Vertel altyd jou gesondheidsorgpraktisyn as jy ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.) Dit is nie bekend dat Dental Melts met ander medisyne reageer nie.

4. HOE OM DENTAL MELTS TE GEBRUIK

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Raadpleeg altyd jou apteker of gesondheidsorgpraktisyn indien jy nie seker is hoe om hierdie medisyne te gebruik nie.

Die tablette moet in die mond opgelos word, verkieslik onder die tong. Vir babas moet die tablette in 'n bietjie water (een teelep) opgelos word en as 'n vloeistof gegee word om die risiko van verstikking te voorkom. Die mond moet vir vry wees van ander sterk smake (bv. tandepasta, peperment, ens.) wanneer die medisyne geneem word. Aangesien absorpsie deur die slymvlies van die mond plaasvind, is dit wenslik om die medisyne vir 'n kort tydjie in die mond te hou.

Die gewone dosis is:

Babas: 1 Tablette opgelos in die mond of in 'n bietjie water elke 30 minute vir 4-5 dosisse. Daarna 1 tablette 3-4 maal per dag.

Kinders: 1-2 Tablette opgelos in mond 3 maal per dag 30 minute voor maaltye.

Behandeling kan voortgaan vir so lank as wat nodig is en kan op enige stadium gestop word wanneer simptome nie meer teenwoordig is nie.

Indien jy meer Dental Melts gebruik as wat nodig is

Daar is geen bekende simptome van oordosis nie. Indien jy 'n nuwe-effek ervaar, raadpleeg jou gesondheidsorgpraktisyn of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As jy vergeet om 'n dosis Dental Melts te neem

Moet nie 'n dubbeldosis neem om 'n oorgeslaande dosis op te maak nie.

5. MOONTLIKE NUWE-EFFEKTE

Daar is geen nuwe-effekte bekend vir Dental Melts nie. Indien jou algemene gesondheid versleg of indien jy enige nuwe-effekte ondervind wanneer jy hierdie medisyne gebruik, raadpleeg jou gesondheidsorgpraktisyn of apteker vir advies.

6. BERGING EN VERNIETIGING VAN DENTAL MELTS

Stoor by of onder 25°C in 'n koel, droë plek en beskerm teen lig en vog. Hou die houder dig gesluit. Moenie in 'n badkamer stoor nie. **Bewaar alle medisyne buite bereik van kinders.** Stuur alle ongebruikte medisyne aan jou apteker terug.

7. VOORLEGGING VAN DENTAL MELTS

Dental Melts is beskikbaar as 50 tablette wat in 'n amber glasbottel met 'n wit HDPE skroef proppe verpak is.

8. IDENTIFIKASIE

Dental Melts is wit, ronde, bi-konvekse tablette met 'n laktose smaak.

9. VERWYSINGSNOMMER

U505 (Wet 101/1965)

10. NAAM EN ADRES VAN DIE APPLIKANT

CoMED Health (Pty) Ltd., 313 Kuitstraat, Waltloo, Pretoria, 0184.
www.comedhealth.co.za (Sien ook www.natura.co.za). Tel: 012 813 9400.

11. DATUM VAN PUBLIKASIE

Junie 2018

12. KOMPLEMENTÊRE MEDIKASIE

Homeopatiese medisyne

Vrywaring: Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir sy kwaliteit, veiligheid of voorgestelde gebruik geëvalueer nie.