PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S0

TEEJEL (gel)

Choline Salicylate

Sugar free

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

Teejel is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use Teejel carefully to get the best results from it.

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

What is in this leaflet

1. What Teejel is and what is it used for

2. What you need to know before you use Teejel

3. How to use Teejel

4. Possible side effects

5. How to store Teejel

6. Contents of the pack and other information

1. What Teejel is and what it is used for

Teejel is a gel that contains the active ingredient choline salicylate which belongs to a group of medicines which provides for effective pain relief and anti-inflammatory action.

Teejel is a gel used to treat pain and inflammation caused by injuries or ulcers in and around the mouth, nose and throat for example: denture sores, fever blisters, cold sores, cheilosis (cracks in the corner of the mouth) and teething discomfort in babies.

2. What you need to know before you use Teejel

Do not use Teejel

- if you are allergic to choline salicylate or other non-acetylated salicylates or any of the other ingredients of Teejel (listed in section 6)
- if you are suffering from a stomach ulcer
- if you are in the third trimester of pregnancy for safety reasons.

Warnings and precautions

Talk to your doctor or health care provider before using Teejel.

Teejel, contains choline salicylate, salicylates have been implicated in Reye's syndrome, a rare but serious illness in children and teenagers with chickenpox and influenza. Consult your doctor before using Teejel in these patients.

Special care should be taken with Teejel in persons with alcohol abuse, because Teejel contains 38,2 % *m/m* ethanol and persons with alcohol abuse must avoid alcohol. The volume of a single dose must not exceed the size of a pea (1 cm).

Children under 12 years of age

The amount of salicylate available in the blood circulation after applying Teejel on the oral mucosa is so minute, that the use of Teejel in children under 12 years of age with teething problems is also possible without medical prescription if used as recommended.

Other medicines and Teejel

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Teejel can increase the effects of anticoagulants such as warfarin.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Use during pregnancy and breastfeeding should be reserved to the express instruction of the doctor. During the last trimester of pregnancy Teejel must not be used for reasons of safety. During the first two trimesters of pregnancy and while breastfeeding the dosage indicated must not be exceeded.

Driving and using machines

Using Teejel will not affect your ability to drive or use machines.

Teejel contains ethanol (alcohol)

Teejel contains alcohol (as a preservative). If you have a history of alcohol abuse, please consult your doctor or pharmacist.

3. How to use Teejel

Do not share medicines prescribed for you with any other person. Always use Teejel exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Teejel should only be used locally (topically) in and around the mouth and nose.

First time use: Unscrew the cap and use the tip on the screw cap to pierce the seal of the tube.

Wash and dry your hands before applying. The usual dose is about 1 cm of the gel (size of a pea) for adults and children above 2 years or about 0,5 cm of the gel (half the size of a pea) for children and infants younger than 2 years, onto your finger and apply it to the affected area.

You may apply Teejel three to four times a day (every 6-8 hours). If this does not provide adequate relief, you may increase the frequency, but should not exceed more than 8 to 10 times a day.

If you use more Teejel than you should

In the event of overdosage,consult your doctor of pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you have ingested or used Teejel in large quantities or used more than what is prescribed, you may experience symptoms associated with either salicylate overdosage or severe intoxication (also see Section 4).

The signs of salicylate overdosage include

- headache
- dizziness
- tingling in ears
- hearing disturbance
- confusion
- sleepiness
- sweating
- nausea and vomiting
- diarrhoea
- fever
- increased breathing

The signs of severe intoxication include

- central nervous disorders
- delirium
- shaking
- disturbance of electrolyte balance
- respiration-induced excessive acidity of blood and body
- metabolism-induced excessive acidity of blood and body
- fever
- loss of body fluid (dehydration)
- unconsciousness
- circulatory and kidney failure

If you forget to use Teejel

Do not use double the dose the next time, but continue application as usual.

If you stop using Teejel

You will not experience any untoward effects if you stop using Teejel.

4. Possible side effects

Teejel can have side effects.

Not all side effects reported for Teejel are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Teejel, please consult your health care provider for advice.

Teejel contains alcohol, when applied on the skin a slight burning sensation may be felt.

Tell your doctor if you notice an intense burning sensation at the site where you have applied Teejel. If any of the following happens, you may have a serious reaction to Teejel, stop using it and contact your doctor:

- if you develop a body rash,
- sudden breathing problems, unexplained wheezing, coughing or asthma or shortness of breath,
- swelling of the mouth, face and lips, tongue or throat.

Tell your doctor if you notice any of the following:

Rare side effects

- Reye syndrome (a condition that causes swelling in the liver and brain);
- gastrointestinal bleeding;
- decrease in blood's ability to clot;
- burning sensation of mucous membranes.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse.

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.

This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of Teejel.

5. How to store Teejel

Store all medicines out of reach of children.

Store at or below 30 °C.

There are no special storage instructions for Teejel.

Do not use after the expiry date stated on the tube/carton.

Returned all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

6. Contents of the pack and other information

What Teejel contains

The active substance is: 1 g gel contains 87,1 mg choline salicylate.

The other ingredients are: 1 g gel contains 2,0 mg sodium cyclamate, 382,0 mg ethanol 96 % *(m/m)*, purified water.

Glycerol, oil of anise, sodium cyclamate and menthol are added as flavourants.

What Teejel looks like and contents of the pack

Teejel is a clear colourless to slightly yellowish, viscous gel with an aniseed-like odour.

Teejel is packed into an aluminium tube that needs to be pierced prior to first use. The tube is sealed with a white, screw cap.

Each tube contains 10 g of gel and is packed into a cardboard carton.

Holder of Certificate of Registration

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