SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
DENCOL 8.71% gel spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 g gel contains;

Active substance(s):
Choline salicylate 87.1 mg

Excipient(s):
Sorbitol (% 70) (E420) 70.0 mg
Polyoxyl 40 hydrogenated castor oil 5.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Gel
Clear colorless gel

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
DENCOL is indicated for the relief of pain in inflammation and wounds in the mouth, pressure and wound sites caused by dental prostheses and jaw orthopaedic devices, teething pain in children older than 6 months.

4.2. Posology and method of administration
Posology/frequency of administration and duration of the treatment:
It is applied by squeezing 1 puff on a cotton or a clean finger and gently massaging the affected area. Unless recommended otherwise by the doctor, it is used as 1 puff 4 times a day.

DENCOL should be used before meals and before going to bed at night**.**

Pediatric population:
It can be used every 6 hours depending on the severity of the pain. It can be used in children under 16 years of age with suspicion of viral flu or chickenpox with the advice of a doctor. Not used in babies under 6 months of age.

Additional information for special populations
Renal/hepatic failure:
The safety and efficacy of DENCOL have not been studied in patients with kidney and liver failure.

Geriatric population
The safety and efficacy of DENCOL have not been studied in elderly.

4.3. Contraindications
DENCOL should not be used in patients who are sensitive to pain and rheumatism medicines, salicylate or any of the excipients.

It is not used in infants under 6 months of age.

4.4. Special warnings and precautions for use

NOT USED WITHOUT CONSULTING DOCTOR IN CHILDREN AND ADOLESCENTS WITH THE SYMPTOMS OF VIRAL FLU OR CHICKEN POX BECAUSE OF THE RARE BUT SERIOUS REYE SYNDROME.

In patients under 16 years of age, it should not be used in cases of viral flu/cold or chicken pox without consulting a physician.

Since DENCOL contains sorbitol (70%) (E420), patients with rare hereditary fructose intolerance problems should not use this medicine.

It may cause nausea and diarrhoea, as well as skin reactions due to its polyoxyl 40 hydrogenated castor oil content.

4.5. Interaction with other medicinal products and other forms of interaction

It should not be used with products containing acetylsalicylic acid in young children.

Due to the sorbitol it contains, it should be used with the advice of a doctor in cases of intolerance to some sugars..

4.6. Fertility, pregnancy and lactation

General advise
Pregnancy category: C

Women of childbearing potential/Birth control (contraception)
It has no adverse effect on women of childbearing potential and contraception.

Pregnancy
It should be used with the advice of a doctor when necessary during pregnancy.

Animal studies are insufficient in terms of effects on pregnancy/and-or/embryonal/fetal development/and-or/natal/and-or/postnatal development. The potential risk to humans is unknown.

Breast-feeding
It should not be used by nursing mothers unless recommended by a doctor.

4.7. Effects on ability to drive and use machines

No adverse effect on ability to drive and use machines.

4.8. Undesirable effects

The specified undesirable effects are categorised according to the following rule:
Very common (≥1/10); common (≥1/100 to <1/10); not common (≥1/1.000 to <1/100); rare (≥1/10.000 to <1/1.000); very rare (<1/10.000), not known (can not be estimated based on available data).

Immune system disorders:

Rare: Allergic reactions, hypersensitivity, anaphylaxis

Nervous System disorders:
Rare: dizziness, ataxia

Vascular disorders:
Rare: excessive fall in blood pressure

Respiratory, thoracic and mediastinal disorders:
Rare: shortness of breath, wheezing

Gastrointestinal disorders:
Rare: vomiting with loss of consciousness

Skin and subcutaneous tissue disorders:
Rare: Urticaria (hives), pruritus, skin rash

In children under the age of 16 and having suspect of viral flu or chicken pox, vomiting may occur with loss of consciousness.

These all very serious side effects are rarely seen.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Turkish Pharmacovigilance Center (TÜFAM). (www.titck.gov.tr; e-mail: tufam@titck.gov.tr; tel.: 800 314 00 08; fax: 0 312 218 35 99).

4.9. Overdose and treatment
Salicylism symptoms such as dizziness, tinnitus, sweating, nausea, vomiting, confusion, hyperventilation, hyperthermia and dehydration may be observed in overdose. At very high doses, coma, cardiovascular collapse and respiratory failure may occur due to central nervous system depression.
In severe intoxications, strong alkaline diuresis should be provided (e.g. with i.v. sodium bicarbonate). Haemodialysis may be necessary in some severe cases..

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: Local oral preparations
ATC Code: A01AD11

5.1. Pharmacodynamic properties
The active substance of Dencol gel sprey, choline salicylate is a non-steroidal anti-inflammatory drug which prevents prostaglandin syntesis by blocking the cyclo-oxygenase and thus reduces pain and inflammation throughout the application.

5.2. Pharmacokinetic properties
General characteristics

Absorption:
The microbicidal activity of the product is not affected by blood, pus and oral secretions. Its effect starts immediately and lasts for 2-3 hours. When choline salicylate is given orally, it is rapidly absorbed from the gastrointestinal tract; when given as a solution, it reaches peak concentration in plasma in about 20 minutes. When given in tablet form, the time to reach peak concentrations is 1.5-2 hours. Nutrients slow down the rate of absorption, but do not affect the extent of absorption..

Distribution:
Choline salicylate is distributed to all body tissues and fluids. It is found in higher concentrations in the liver and kidney. It rapidly crosses the placenta and passes into breast milk. The binding of salicylic acid to proteins may vary depending on the dose and the individual. Although binding is 90-95% at low doses, it decreases to 25-60% when plasma concentrations increase.

Biotransformation:
Salicylate compounds are metabolised to salicylic acid, mainly in the gastrointestinal tract, liver and blood, and salicylic acid is metabolised mainly in the liver.

Elimination:
The elimination half-life of salicylic acid is 2-3 hours after a single dose or low doses and ≥ 20 hours after repeated or very high doses, depending on dose and urinary pH, and may vary between 5 and 18 hours. Salicylate salts are excreted from the body by the renal route as free salicylic acid and conjugated metabolites.

5.3. Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS
6.1. List of excipients
Chlorhexidine gluconate
Glycerin
Sorbitol (70 %) (E420)
Povidone K90
Polyoxyl 40 hydrogenated castor oil
Citric acid monohydrate
Deionized water

6.2. Incompatibilities
There is no evidence of incompatibility with any drug or substance for DENCOL.

6.3. Shelf life
24 months

6.4. Special precautions for storage
Store at room temperature below $25^{O}C$.

6.5. Nature and contents of container
DENCOL is marketed as 20 g in HDPE opaque bottles with PP safety sleeve, sealed with PE piston spray cap..

6.6. Special precautions for disposal and other handling
Any unused product or waste material should be disposed in accordance with regulations "Medical Waste Control Regulation" and"Packaging Waste Control".

7. MARKETING AUTORIZATION HOLDER
Berko İlaç ve Kimya Sanayi A.Ş.
Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul
0 216 456 65 70 (Pbx)
0 216 456 65 79 (Fax)
info@berko.com.tr

8. MARKETING AUTORIZATION NUMBER(S)
225/65

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
First authorization date: 25.06.2010
Renewal of the authorization: 09.06.2015

10. DATE OF REVISION OF THE TEXT
01.04.2018