SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TIRECORT 2% + 0.1% Cream

2. QUALITIVE and QUANTITIVE COMPOSITION

Active ingredient

Fusidic acid (cow's milk)	20 mg / g
Betamethasone valerate	1 mg / g

Excipient(s):

Cetostearyl alcohol	80 mg / g
Butyl hydroxy anisole	0.04 mg / g

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.
White cream.

4. CLINICAL PARTICULAR

4.1. Therapeutic indications

TIRECORT is indicated in inflammatory dermatoses when bacterial infection is confirmed or suspected. Inflammatory dermatoses include atopic eczema, discoid eczema, stasis eczema, seborrheic dermatitis, contact dermatitis, chronic lichen simplex, psoriasis and discoid lupus erythematosus.

4.2. Posology and method of administration

Posology/the frequency and duration of adminstration:
Applied 2 or 3 times a day to the lesions.

Mode of administration:
Applied externally on the skin.

TIRECORT treatment should be terminated as soon as disease get better. TIRECORT treatment should not last longer than 4 weeks before patients being re-evaluated.

Following long-term treatment while TIRECORT is being terminated, the dose of medicine should be terminated by gradually reducing.

Additional information on special populations:

Renal/Hepatic Failure:
There is no need to adjust the dose in renal failure.

Caution should be exercised in hepatic failure because betamethasone is metabolized in the liver.

The pediatric population:
The use of medicines containing topical corticosteroids in children should be limited to the lowest amount which effective treatment can be obtained. Chronic corticosteroid treatment may affect the growth and development of a child.

It is not recommended for use in the childhood age group unless absolutely necessary.

TIRECORT should not be used in the treatment of diaper rash in infants.

The geriatric population:
There are no data regarding with the use in the elderly.

4.3. Contraindications

Topical corticosteroids are contraindicated in case of viral and fungal skin infection, tuberculosis, syphilis, perioral dermatitis, acne rosacea and ulcerative. Also TIRECORT is contraindicated in case of known hypersensitivity to any of the ingredients in the composition.
TIRECORT is contraindicated in children under 1 year of age.

4.4. Special warnings and precautions for use

Long-term continuous topical therapy should be avoided, particularly on the face, joint, curvy areas, in infants and children. Adrenal suppression can occur even without occlusion. Atrophic changes may occur on the face and to a lesser degree in other parts of the body, after prolonged treatment with potent topical steroids. Caution should be exercised when TIRECORT is used near the eye, glaucoma might result if the preparation enters the eye. It should also be used only in the presence of perianal or genital itching, briefly. Systemic chemotherapy is required if bacterial infection persists. TIRECORT may mask existing infection and delay healing.

TIRECORT treatment should not be continued for more than 4 weeks. While the treatment is being terminated, medicine should not be discontinued suddenly, the dose should be discontinued by gradually reducing.

TIRECORT contains cetostearyl alcohol and butyl hydroxyl anisole which may cause local skin reactions (e.g. contact dermatitis).

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

Any drug interactions have not been reported regarding with TIRECORT application.

Additional information on special populations:
No interaction studies have been performed on specific populations.

Pediatric populations:
No interaction studies have been performed on pediatric populations.

4.6. Pregnancy and lactation

General advice
Pregnancy category: C.

Women of childbearing potential/Birth control (Contraception)
There is no information about not being used in women of childbearing potential and birth control.

Pregnancy
Studies in animals have shown reproductive toxicity (Please see Section 5.3). The potential risk for humans is unknown.
There is not enough data on the use of TIRECORT in pregnant women. It should not be used in pregnancy unless it is necessary.

Breast-feeding
It is not known whether TIRECORT is excreted in human milk. The excretion of TIRECORT with milk has not investigated in animals. While is decided about the discontinuation of breastfeeding or TIRECORT treatment/ avoid from the treatment, benefits of breastfeeding in terms of children and benefits of TIRECORT treatment in terms of breastfeeding mothers should be considered.
Application of TIRECORT is not recommended on the breast in breastfeeding mothers.

Fertility
There are no fertility toxicity in studies conducted animals. There is no data on the effect of fusidic acid on fertility.

4.7. Effects on ability to drive and use machines
No effect on driving and using machine use has been reported.

4.8. Undesirable effects
Adverse reactions that are considered to be drug related are listed below:

Very common (≥1/10),
Common (≥1/100 and <1/10)
Uncommon (≥1/1,000 and <1/100)
Rare (≥1/10,000 and <1/1,000)
Very rare (<1/10,000)
Not known (can not be estimated from the available data)

Immune system disorders
Very rare: Hypersensitivity

Skin and subcutaneous tissue disorders
Uncommon: Eczema (condition aggravated), urticaria, skin rash in the form of dermatitis contact and skin redness, skin irritation, itching, skin dryness, burning and stinging sensation on skin.

Very rare: Atrophy, telangiectasia.

Undesirable class effects of corticosteroids include: atrophy, telangiectasia, skin striae, folliculitis, hypertrichosis, perioral dermatitis, alergic contact dermatitis, depigmentation, glaucoma and adrenocortical suppression may also occur with prolonged use of topical corticosteroids.

Reporting of side effects
If you get any side effects, stated or not stated in the Patient Information Leaflet, talk to your doctor or pharmacist. Also, please report the side effects you have to Turkish Pharmacovigilance Center (TÜFAM) by either clicking to "Reporting Drug Side Effect" icon on www.titck.gov.tr or calling side effect reporting line via 0 800 314 00 08. By reporting the side effects you can help provide more information on the safety of this medicine.

TÜFAM	Turkish Pharmacovigilance Center www.titck.gov.tr

4.9. Overdose and treatment

The long-term use of topical corticosteroids may cause secondary adrenal insufficiency, usually by reversible pituitary-adrenal function suppression. Symptomatic treatment should be applied in such cases.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, powerful (in combination with antibiotics)
ATC code: D07CC01

TIRECORT ombines the well-known anti-inflammatory and antipruritic effects of betamethasone with the potent topical antibacterial action of fusidic acid.

Fusidic acid is an active antibiotics mainly against Gram-positive bacteria and is a very active antibiotics against especially *Staphylococcus aureus*, *Propionibacterium acnes* and *Corynebacterium*, is effective against microorganisms resistant to other antibacterial and penicillin. Concentrations of 0.03 to 0.12 microgram per ml inhibit nearly all strains of *S. aureus*. Betamethasone valerate is in the powerful corticosteroid group, when applied locally is effective by suppressing of local immune reactions such as vasodilation, swelling and pain. When applied topically, the antibacterial activity of fusidic acid is not diminished in the presence of betamethasone.

5.2. Pharmacokinetic properties

General properties

There are no data which define the pharmacokinetics of TIRECORT in human.

Absorption:
Betamethasone is absorbed following topical administration to the inflamed skin. The degree of absorption is depend on various factors including skin condition and site of

application. The systemic penetration of fusidic acid from intact human skin is negligible.

Distribution:
There is no data about the distribution of TIRECORT.

Biotransformation:
Betamethasone is metabolised largely in the liver but also to a limited extent in the kidneys.
Fusidic acid is metabolized intensely in the liver.

Elimination:
The inactive metabolites of TIRECORT are excreted with the urine.
Fusidic acid is excreted mainly in the bile with little excreted in the urine.

5.3. Preclinical safety data
Have not been reported.

6. PHARMACEUTICAL PROPERTIES

6.1. List of excipients
Macrogol cetostearyl ether 20
Cetostearyl alcohol
White soft paraffin
Chlorocresol
Butyl hydroxy anisole (E320)
Liquid paraffin
Purified water
Sodium dihydrogen phosphate dihydrate
Sodium hydroxide
Hydrochloric acid

6.2. Incompatibilities
Not applicable.

6.3. Shelf life
24 months.

6.4. Special precautions for storage
Keep at room temperature below 30 ° C.

6.5. Nature and contents of container
30 grams of aluminum tube and plastic (HDPE) cap

6.6. Special precautions for disposal and other handling
Unused products or waste materials should be disposed in accordance with the "Regulation for the Control of Medical Wastes" and the "Regulation for the Control of Packages and Package Wastes".

7. MARKETING AUTHORISATION HOLDER

Humanis Saglik A.S.
Istanbul/TURKEY

8. MARKETING AUTHORISATION NUMBER(S)

07856/09529/NMR/2022
09448/08768/VAR/2023

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation : Oct 1, 2022
Date of latest renewal: :

10. DATE OF REVISION OF THE TEXT

06.02.2020