SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Product Name

T3 Ada Gel 0.1%

1.2 Strength

Adapalene 0.1% w/w

1.3 Pharmaceutical Dosage Form

Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative

Adapalene 0.1% w/w

2.2 Quantitative

1g gel contains 1mg adapalene

3. PHARMACEUTICAL FORM

Gel

Off white opaque viscous gel with characteristic odour

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Acne vulgaris in which comedones, papules and pustules predominate.

4.2 Posology and method of administration

Apply once a day to affected areas after washing in the evening before retiring. A thin film of the gel should be applied, avoiding eyes, lips and mucous membranes.

In patients where it was necessary to reduce the frequency of application or to temporarily discontinue treatment, frequency of application may be restored, or therapy resumed once it is judged that the patient can once again tolerate the treatment. If patients use cosmetics, these should be non-comedogenic and non-astringent.

4.3 Contraindications

Hypersensitivity to adapalene or any of the ingredients of the product.
Pregnancy *(see section 4.6 Pregnancy and lactation).*
Women planning a pregnancy.

4.4 Special warnings and special precautions for use

If a reaction suggesting sensitivity or chemical irritation occurs, use of the medication should be discontinued. If the irritation is not severe, patients should be instructed to reduce the frequency of application or discontinue use temporarily until symptoms subside, or discontinue use altogether.

If patients use cosmetics, these should be non-comedogenic and non-astringent. Only oil-free moisturisers should be used to relieve dry facial skin.

Because T3 Ada may cause some irritation, it is possible that simultaneous use of abrasive cleansers, astringent or strong drying agents or irritant products may cause additive irritant effects.

Exposure to sunlight, including sunlamps, should be minimised during use of adapalene.

T3 Ada should not be applied to skin abrasions, eczematous skin, or sunburned skin.

Use in children: safety and effectiveness in children below the age of 12 have not been established.

4.5 Interaction with other FPPs and other forms of interaction

There are no known interactions with other medications which might be used topically and concurrently with T3 Ada. However other retinoids or drugs with a similar mode of action should not be used concurrently with adapalene.

As T3 Ada has the potential to produce local irritation in some patients, concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol, astringents, spices or lime rind) should be approached with caution. Particular caution should be exercised in using preparations containing sulfur, resorcinol, or salicylic acid in combination with T3 Ada. If these preparations have been used, it is advisable not to start therapy with T3 Ada until the effects of such preparations in the skin have subsided. However, topical anti-acne treatments eg. erythromycin (up to 4%) or clindamycin phosphate (1% as the base) solutions or benzoyl peroxide water-based gel up to 10%, may be used in the morning when T3 Ada is used at night when there is no mutual degradation or cumulative irritation.

4.6 Pregnancy and lactation

Use in pregnancy: There are no adequate and well-controlled studies done in pregnant women. Adapalene should be used during pregnancy only if the potential benefit outweighs the potential risk to the foetus. Orally administered retinoids have been associated with congenital abnormalities. When used in accordance with the prescribing information, topically administered retinoids are generally assumed to result into low systemic exposure due to minimal dermal absorption. However, there could be individual factors (e.g., damaged skin barrier, excessive use) that contribute to an increased systemic exposure. T3 Ada Gel is contraindicated *(see section 4.3 Contraindications)* in pregnancy, or in women planning a pregnancy. If the product is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued.

Use in lactation: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when T3 Ada is administered to a nursing mother.

4.7 Effects on ability to drive and use machines

Unknown

4.8 Undesirable effects

A feeling of warmth, burning, pruritus, dryness, scaling or slight stinging may occur following application. The following additional adverse experiences were reported in approximately 1% or less of patients: skin irritation, burning/ stinging, erythema, sunburn, and acne flares. Most reactions occurred within 1 month of the initiation of therapy and were generally observed to resolve with continued use of the product or temporary adjustment of the treatment schedule.

4.9 Overdose

T3 Ada is not to be taken orally and is for topical use only. Absorption does not occur to any great extent with topical use, hence overdosage is unlikely. If the medication is applied excessively, no more rapid or better results will be obtained and marked redness, peeling, or skin discomfort may occur.

In the event of accidental ingestion, if ingestion is recent, the stomach should be emptied immediately by gastric lavage. (Chronic ingestion of the drug may lead to the same side effects as those associated with excessive oral intake of vitamin A).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Adapalene is a chemically stable retinoid-like compound. Its biochemical and pharmacological profile has been demonstrated to possess anti-inflammatory properties. Profile studies have demonstrated that adapalene is a modulator of cellular differentiation, keratinisation, and inflammatory processes all of which represent important features in the pathology of acne vulgaris. Mechanistically, adapalene binds to specific retinoic acid nuclear receptors but does not bind to cytosolic receptor protein.

Although the exact mode of action of adapalene is unknown, current evidence suggests that topical adapalene normalises the differentiation of follicular epithelial cells resulting in decreased microcomedone formation.

5.2 Pharmacokinetic properties

Absorption of adapalene through human skin is low. Only trace amounts (< 0.25 ng/ml) of parent substance have been found in the plasma of acne patients following chronic topical application of adapalene in controlled clinical trials. Excretion appears to be primarily by the biliary route.

5.3 Preclinical safety data

Unknown

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylparaben, Phenoxyethanol, Carbomer, Allantoin, Disodium Edetate, Polyethylene Glycol 400, Butylene Glycol, Glycerin, Sodium Hydroxide and Purified Water

6.2 Incompatibilities

All excipients are compatible amongst themselves and with the active ingredient.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C. Keep out of reach of children. Keep container well closed.

6.5 Nature and contents of container

25g in aluminium tube

6.6 Instructions for use and handling

No special requirement

7. MARKETING AUTHORISATION HOLDER

HOE Pharmaceuticals Sdn. Bhd., Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor Darul Ehsan, MALAYSIA.

8. MARKETING AUTHORISATION NUMBERS

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10. DATE OF REVISION OF THE TEXT

18th August 2020