1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

ASKEMEL OINTMENT
(Resorcinol and Sulphur Ointment)

2. Qualitative and quantitative composition

2.1 Label Claim

Composition:

Resorcinol USP	2 % w/w
Sulphur	8 % w/w
Excipients	q.s.

2.2 Quantitative Composition

Batch Size: 100 kg

Sr. No.	Ingredients	Spec.	Label Claim (w/w)	Over.	Std. Qty. (in kg)	Property
1.	Resorcinol	USP	2 %	5 %	2.100	Active
2.	Sulphur	IHS	8 %	5 %	8.400	Active
3.	Ethyl Alcohol (Ethanol)	IHS	--	--	2.000	Astringent/ Preservative
4.	Anhydrous Lanoline	IHS	--	--	0.250	Moisturizer
5.	Cetostearyl Alcohol	BP	--	--	2.500	Emulsifier
6.	Hard Paraffin Wax	BP	--	--	13.000	Antioxidant
7.	Microcrystalline Wax	USP	--	--	14.000	Thickener
8.	Light Liquid Paraffin	BP	--	--	57.750	Moisture Retention
9.	Propylene Glycol	BP	--	--	2.000	Humectants

3. Pharmaceutical form

Ointment

4. Clinical particulars

4.1 Therapeutic indications

It is indicated:

For the treatment of acne

Clears up most acne pimples

Helps prevent new acne pimples

4.2 Posology and method of administration

Cover the entire affected area with a thin layer one to three times daily.

Method of administration

Topical administration only.

4.3 Contraindications

Hypersensitivity to active substance and any of the excipients.

Existing skin rash or irritation

4.4 Special warnings and precautions for use

When using resorcinol and sulfur combination, do not use any of the following preparations on the same affected area as resorcinol and sulfur, unless otherwise directed by your doctor:

Abrasive soaps or cleansers

Alcohol-containing preparations

Any other topical acne preparation or preparation containing a peeling agent (for example, benzoyl peroxide, salicylic acid, or Tretinoin [vitamin A acid])

Cosmetics or soaps that dry the skin

Medicated cosmetics

Other topical medicine for the skin

To use any of the above preparations on the same affected area as resorcinol and sulfur may cause severe irritation of the skin.

Do not use any topical mercury-containing preparation, such as ammoniated mercury ointment, on the same affected area as resorcinol and sulfur. To do so may cause a foul odor, may be irritating to the skin, and may stain the skin black.

Resorcinol and sulfur (depending on the product you are using) may darken light-colored hair.

4.5 Interaction with other medicinal products and other forms of interaction

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. Tell your healthcare professional if you are taking any other prescription or nonprescription (over-the-counter [OTC]) medicine.

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

4.6 Fertility, pregnancy and lactation

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

4.7 Effects on ability to drive and use machines

There are no and negligible influence on ability to drive and use machines.

4.8 Undesirable effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor as soon as possible if any of the following side effects occur:

Less common or rare

- Skin irritation not present before use of resorcinol and sulfur
- Symptoms of resorcinol poisoning
- Diarrhea, nausea, stomach pain, or vomiting
- dizziness
- drowsiness
- headache (severe or continuing)
- nervousness or restlessness
- slow heartbeat, shortness of breath, or troubled breathing
- sweating
- unusual tiredness or weakness

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- Redness and peeling of skin (may occur after a few days)

Less common

- Unusual dryness of skin

4.9 Overdose

Not Known

5. Pharmacological properties

5.1 Pharmacodynamic properties

Data regarding the specific mechanisms of action of resorcinol does not appear to be readily accessible in the literature. Nevertheless, the effectiveness of the agent in treating various topical, dermatological conditions by eliciting antibacterial and keratolytic actions appears to stem from resorcinol's propensity for protein precipitation. Ln particular, it appears that resorcinol indicated for treating acne, dermatitis, or eczema in various skin care topical applications and peels revolves around the compound's ability to precipitate cutaneous proteins from the treated skin.

5.2 Pharmacokinetic properties

In vitro and in vivo studies have demonstrated that resorcinol can inhibit peroxidases in the thyroid and subsequently block the synthesis of thyroid hormones and cause goiter. Resorcinol interferes with the iodination of tyrosine and the oxidation of iodide. In an in vitro study involving lactoperoxidase (LPO) and thyroid peroxidase (TPO), it was shown that the mechanism of these two enzymes can become irreversibly inhibited by way of a suicide inactivation by resorcinol.

It is believed that the Fe3+ of the porphyrin residue of the peroxidase to is oxidised to Fe4+ by hydrogen peroxide with the transfer of an oxygen radical. ln LPO and TPO, the resulting π-cation radical of the porphyrin can isomerize to a radical cation with the radical in an aromatic side chain of the enzyme. The latter radical can bind, in a pH-dependent reaction,

covalently and irreversibly to the resorcinol radical formed during regular oxidation of resorcinol and this reduces the activity of the enzyme greatly. While the inactivation of the enzyme and the binding of resorcinol to the enzyme may be largely increased by the presence of 0.l nM iodide, increasing the iodide concentration to 5 mM reduced the resorcinol binding to the enzyme by one quafier but increased the enzyme activity, determined as the rate of iodination of tyrosine, more than proportionally from 6.20/o to 44.10 . Nevertheless, the role played by iodide ions in the irreversible inactivation of the enzymes is not yet fully elucidated. Ultimately, such in vitro and in vivo data propose that the anti-thyroidal activity of resorcinol is caused by inhibition of thyroid peroxidase enzymes, resulting in decreased thyroid hormone production and increased proliferation due to an increase in the secretion of TSH (thyroid stimulating hormone). The iodination process is catalyzed by a haem-containing enzyme, and resorcinol is known to form covalent bonds with haem.

Absorption: The dermal absorption of resorcinol seems to be low (< l%) when applied on healthy and intact skin. The agent absorbed very slightly under normal conditions & the absorption was lower when applied to the scalp than to clean shaven

skin due to a strong fixation by the hair.

Metabolism: Specific data regarding the volume of distribution of resorcinol is not readily available, although it is believed that the compound's volume of distribution is considered large, owing to resorcinol's profile as a lipid-soluble compound.

Route of elimination: Specific data regarding the route of elimination of resorcinol is not readily available, although the major metabolite of resorcinol found in the urine was its glucuronide.

6. Pharmaceutical particulars

6.1 List of excipients

Ethyl Alcohol (Ethanol) BP

Anhydrous Lanoline IH

Cetostearyl Alcohol BP

Hard Paraffin Wax BP

Microcrystalline Wax USP

Light Liquid Paraffin BP

Propylene Glycol BP

6.2 Incompatibilities

None known

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30° C.

6.5 Nature and contents of container

20 grams Ointment packed in collapsible Aluminium tubes embossed with batch number, manufacturing date and expiry dates packed in unit box with an insert.

7. Marketing Authorization Holder

HAB PHARMACEUTICL & RESEARCH LTD.

10, Pharmacity, Sidcul, Selaqui,

Dehradun, Uttarakhand 248011

8. Marketing authorization number(s)

9. Date of first Authorization/Renewal of the Authorization:

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10. Date of Revision:

November 2021