SUMMARY OF PRODUCT CHARACTERISTICS

VOLINI GEL

(Diclofenac diethylamine, Linseed oil, Methyl Salicylate and Racementhol Gel)

1. NAME OF THE MEDICINAL PRODUCT

VOLINI GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

VOLINI GEL contains:

Diclofenac Diethylamine BP	1.16% w/w
(equivalent to Diclofenac Sodium BP)	1 % w/w
Linseed Oil BP	3% w/w
Methyl Salicylate BP	10% w/w
Race menthol BP	5% w/w
Preservative:	
Benzyl Alcohol BP	1 % w/w
Gel base	q.s.

3. PHARMACEUTICAL FORM

Topical gel

Description: White, smooth, homogenous gel, free from lumps and foreign particles, filled in Printed Lami tube with PP stand up screw cap.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications [1]

Volini Gel is indicated:

For the local symptomatic relief of pain and inflammation in:

- trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains and bruises.
- localised forms of soft tissue rheumatism.

For the relief of pain of non-serious arthritic conditions

4.2 Posology and method of administration [1]

Adults and children 14 years and over: Volini Gel should be rubbed gently into the skin. Depending on the size of the affected site to be treated, 2-4g should be applied 3-4 times a day. The maximum daily dose is 16g. Therefore, the maximum weekly dose is 112g.

A period of at least 4 hours should be left between applications. The dose should not be applied more than 4 times in a 24 hour period.

If symptoms persist after 7 days or get worse at any time, medical advice should be sought. Not to be used for more than 7 days unless recommended by a doctor.

For arthritis pain it may be necessary to apply the gel for up to 7 days (to allow its effect to build up on the joint) before an improvement in pain is noticed. The gel can be used for up to 14 days under pharmacy supervision.

After application, the hands should be washed unless they are the site being treated.

Use in the elderly: The usual adult dosage may be used.

Children and adolescents: There are insufficient data on efficacy and safety available for the children and adolescents below 14 years of age (see Section 4.3). In children aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

Method of administration: Topical

4.3 Contraindications [1, 2]

Volini Gel is contraindicated in:

- Patients with or without chronic asthma in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by acetylsalicylic acid (aspirin) or other non- steroidal anti-inflammatory drugs (NSAIDs)
- Patients with a known hypersensitivity to diclofenac, acetylsalicylic acid or non-steroidal anti-inflammatory drugs or linseed oil or racementhol or methyl salicylate or any of the excipients
- Third trimester of pregnancy
- The use in children and adolescents aged less than 14 years is contraindicated

4.4 Special warnings and precautions for use [1, 2]

The possibility of systemic adverse events from application of Volini Gel cannot be excluded if the preparation is used on large areas of skin and over a prolonged period. This includes hypersensitivity and asthma (renal disease has also been reported).
Concomitant use of systemic NSAIDs should be cautioned since the possibility of an increase in incidence of untoward effects, particularly systemic side effects, cannot be ruled out.

Volini Gel should be applied only to intact, non-diseased skin and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes, and should not be ingested.
Discontinue the treatment if a skin rash develops after applying the product.

Patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity.

Patients with a history of or active peptic ulceration. Some possibility of gastro-intestinal bleeding in those with a significant history of this condition has been reported in isolated cases.

Like other drugs that inhibit prostaglandin synthetase activity, diclofenac and other NSAIDs can precipitate bronchospasm if administered to patients suffering from or with a previous history of, bronchial asthma.

This medicine contains propylene glycol, which may cause mild localised skin irritation in some people.

This medicine can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard.

Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction [1, 2, 3]

Since systemic absorption of diclofenac from a topical application is very low such interactions are very unlikely. There are no known interactions with VOLINI GEL but for a list of interactions known with oral diclofenac the data sheet for oral

dosage forms should be consulted.

There have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin. Menthol has also been reported to interact with warfarin (when taken orally), decreasing its effectiveness.

4.6 Pregnancy and lactation [1, 2]

Pregnancy

The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. With reference to experience from treatment with NSAIDs with systemic uptake, the following is recommended:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. An increased risk of miscarriage and of cardiac malformation and gastroschisis has been reported after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been reported to result in increased pre- and post-implantation loss and embryo- fetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the fetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligohydroamniosis;

The mother and the neonate, at the end of pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, diclofenac is contraindicated during the third trimester of pregnancy.

Lactation

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However,

at therapeutic doses of Volini Gel, no effects on the suckling child are anticipated. Because of a lack of reported studies in lactating women, the product should only be used during lactation under advice from a healthcare professional. Under this circumstance, Volini Gel should not be applied on the breasts of nursing mothers, nor do elsewhere on large areas of skin or for a prolonged period of time (see Section 4.4).

Fertility
There are no data reported on the use of topical formulations of diclofenac and its effects on fertility in humans.

4.7 Effects on ability to drive and use machines[1, 2]

Volini Gel has no influence on the ability to drive and use machines.

4.8 Undesirable effects [1, 2, 3]

Local: This medicine is usually well tolerated. Local irritation, erythema, pruritus or dermatitis may occasionally occur. Skin photosensitivity, desquamation, discolouration and bullous or vesicular eruptions have been reported in isolated cases. Patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity.

General: Systemic absorption of this medicine is low compared with plasma levels obtained following oral forms of diclofenac. However, where this medicine is applied to a relatively large area and over a prolonged period, the possibility of systemic side effects cannot be completely excluded.

Asthma has been rarely reported in patients using topical NSAID preparations.

Adverse reactions are ranked under heading of frequency, the most frequent first, using the following convention: very common (> 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (< 1/10,000), not known: cannot be estimated from the available data.

Immune system disorder:	
Very rare:	Hypersensitivity (including urticaria), angioneurotic oedema.
Infections and infestations:	
Very rare:	Rash pustular.
Respiratory, thoracic and mediastinal disorders	
Very rare:	Asthma.
Skin and subcutaneous tissue disorders	
Common:	Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus

Rare:	Dermatitis bullous
Very rare:	Photosensitivity reaction
Not known	Desquamation, skin discoloration

Known side effects of menthol – contact dermatitis or eczema, hypersensitivity reactions characterised by urticaria, flushing and headache.

4.9 Overdose [1, 2, 3]

If you swallow, seek medical advice immediately

Diclofenac

The low systemic absorption of topical diclofenac renders overdose very unlikely. However, undesirable effects, similar to those reported following an overdose of diclofenac tablets, can be expected if the product is inadvertently ingested.

Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from diclofenac overdosage. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression; specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

In the event of accidental ingestion, resulting in significant systemic adverse effects, general therapeutic measures normally adopted to treat poisoning with non-steroidal anti- inflammatory medicines should be used. The use of activated charcoal should be considered, especially within a short time of ingestion.

Methyl Salicylate

When used externally as directed, overdose is unlikely. However, symptoms of systemic salicylate poisoning have been reported after the application of salicylates to large areas of skin or for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested.

Common features of salicylate poisoning include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common.

Acidosis may increase salicylate transfer across the blood brain barrier.
Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopaenia, increased INR/PTR, intravascular coagulation, renal failure and noncardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

Activated charcoal may be administered if significant quantities have been ingested within an hour of presentation. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema. Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700mg/L (5.1mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

Menthol
Ingestion of significant quantities of menthol is reported to cause symptoms, which include severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness, epigastric pain, headache, dizziness, oropharyngeal burning, delirium, muscle twitching, epileptiform convulsions, CNS depression and coma. Breathing is difficult and the breath has a characteristic odour; anuria may occur. Death from respiratory failure or status epilepticus may occur; fatalities in children have been reported from 1g.

Supportive care, including anticonvulsant therapy, is the mainstay of treatment of menthol intoxication. Gastric lavage may be considered if the patient presents within 1 hour of ingestion; any convulsions must be controlled first. Activated charcoal may be given orally.

5. PHARMACOLOGICAL PROPERTIES[1,2,3,4]

5.1 Pharmacodynamic properties [1,2,3,4]

Pharmacotherapeutic group: Topical products for joint and muscular pain.

ATC Code: M02AA15 (Anti-inflammatory preparations, non-steroids for topical use).

Mechanism of action

Volini Gel contains diclofenac, methyl salicylate and racementhol and linseed oil. It is an anti-inflammatory and analgesic preparation designed for topical application. Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and anti- inflammatory properties. Diclofenac exerts its therapeutic effects primarily through inhibition of prostaglandin synthesis by cyclo-oxygenase 2 (COX-2).

Menthol relieves itching, dilates the vessels causing a sensation of coldness followed by an analgesic effect.

Methyl salicylate has the actions of the salicylates. It is readily absorbed through the skin and has counter-irritant properties.

5.2 Pharmacokinetic properties [1, 2, 3]

Diclofenac

Diclofenac has been reported to be absorbed through the skin after topical application. In healthy volunteers approximately 6% of the dose applied has been reported to be absorbed, as determined by urinary excretion of diclofenac and its hydroxylated metabolites. Findings in patients reported that diclofenac penetrates inflamed areas following local application. Synovial fluid and tissue levels of diclofenac are higher than those detected in plasma.

Methyl salicylate

Like other salicylates, methyl salicylate may be absorbed through intact skin. Percutaneous absorption is enhanced by exercise, heat occlusion, or disruption of the integrity of the skin. The amount absorbed will also be increased by application to large areas of skin.

Results from a study in healthy subjects reported that a considerable amount of salicylic acid may be absorbed through the skin after topical application of product containing methyl salicylate. Both the rate and extent of absorption have been reported to be increased after repeated application; It was reported that the bioavailability of the ointment preparation used in the study increased from 15% after the second dose to 22% after the third to eighth dose.

Menthol

After absorption, menthol has been reported to be excreted in the urine and bile as a glucuronide. The systemic absorption of camphor, menthol, and methyl salicylate from dermal patches containing all three ingredients has been reported in the literature. The absolute bioavailability of these compounds could not be reported from the study, but there did not appear to be any substantial systemic accumulation even after unrealistically high exposure for prolonged periods.

5.3 Preclinical safety data [1, 2, 3]

None

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol, Carbomer 934, Polyoxyl 40 Hydrogenated castor oil, Propylene glycol, Butylated hydroxy toluene, Citric acid monohydrate, Disodium edetate, Diethylamine

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

18 Months

6.4 Special precautions for storage

Do not store above 30°C. Do not freeze.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.
Distribution category: POM

6.5 Nature and contents of container

30g & 50 g gel packed in Lami tube and such 1 tube packed in a carton along with pack insert.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements".

7. MARKETING AUTHORISATION HOLDER

Sun Pharmaceuticals Industries Limited
Sun House, Plot No. 201 B/1,
Western Express Highway, Goregaon (E)
Mumbai - 400 063, Maharashtra, INDIA,

Manufactured in India by:

Sun Pharmaceutical Industries Ltd.
Kh. No. 1335-1340, Near EPIP-I
Vill-Bhatoli Kalan, Baddi,
Distt. Solan, H.P. 173205

8. MARKETING AUTHORISATION NUMBER(S)

Not applicable

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10. DATE OF REVISION OF THE TEXT

Oct-2024

REFERENCES:

1. Summary of Product Characteristics of Voltarol Osteoarthritis Joint Pain Relief 1.16% Gel, GlaxoSmithKline Consumer Healthcare, UK, April 2023.
2. Summary of Product Characteristics of Voltarol Back and Muscle Pain Relief 1.16%; Voltarol Pain-eze Emulgel, GlaxoSmithKline Consumer Healthcare, UK, April 2021.
3. Summary of product characteristics of Radian B Muscle Rub, Thornton & Ross Ltd, UK, revised in September 2019.
4. Martindale: The Complete Drug Reference. London: Pharmaceutical Press, electronic version, 2009.

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