SUMMARY OF PRODUCT CHARACTERISTICS

1. Trade Name of Medicinal Product

Soludol Tablets
(Diclofenac Dispersible Tablets)

2. Qualitative and Quantitative Composition

Ingredients	Quantity mg / tablet	Active / Inactive	Reference to standard	Function
Diclofenac Free Acid	46.50	Active	In-house	NSAID
Croscarmellose Sodium (Ac-Di-Sol)	14.60	Inactive	BP	Disintegrant
Colloidal Anhydrous Silica (Aerosil-200)	4.60	Inactive	BP	Glidant
Hydrogenated Castor Oil (Cutina HR)	1.60	Inactive	USP-NF	Lubricant
Microcrystalline Cellulose (Avicel PH-101)	160.00	Inactive	BP	Diluent
Pineapple Flavour DC 106 PH(Dry)	3.00	Inactive	In-house	Flavouring agent
Sodium Saccharin	1.50	Inactive	BP	Sweetening
Sodium Starch Glycollate	29.00	Inactive	BP	Disintegrant
Talc	1.60	Inactive	USP	Glidant
Tartrazine Yellow Lake	1.00	Inactive	In-house	Coloring agent
Total	**263.40 mg**			

3. Pharmaceutical Form

Dispersible Tablets
Description: Light yellow, round, flat, scored, plain dispersible tablets

4. Clinical Particulars

4.1 Therapeutic Indications

Soludol is indicated for post-operative and post-traumatic pain; flare up of joint pain, myalgia, sprains and strains, painful dental conditions, primary dysmenorrhea, headache, tonsillitis, etc.

4.2 Posology and Method of Administration

As a rule, the daily dose for adults is 1 tablet, 2 or 3 tablets, 2 or 3 times a day. The drug should be taken with or after meals.

Soludol tablets should preferably be dispersed in a glass of water. Stir the water to fully disperse the tablet. Drink the solution, once the tablet has completely dispersed.

Soludol should not be used in children below 14 years of age.

4.3 Contraindications

- Hypersensitivity to diclofenac.
- Peptic ulcer.
- In asthmatic patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or by other drugs with prostaglandin-synthetase inhibiting activity.

4.4 Special Warnings and Special Precautions for Use

- Close medical surveillance is required in patients with symptoms indicative of gastro-intestinal disease, a history of dyspepsia, Crohn's disease, ulcerative colitis, etc., and in patients with blood coagulation disorders, and those with severe cardiac, hepatic or renal disease.

- Caution should be exercised in elderly patients, who are generally more likely to experience side effects.

- In patients receiving long-term treatment, it is advisable to check blood counts at intervals and monitor hepatic and renal functions.

- When given along with oral anticoagulants or oral Antidiabetics, as a precaution the dosage of these drugs should be carefully adjusted in accordance with prothrombin time and blood glucose levels respectively.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Drug interactions have been reported with the simultaneous administration of diclofenac with lithium, digoxin, methotrexate, cyclosporine & diuretics etc.

4.6 Pregnancy and Lactation

The use of Soludol during pregnancy should, if possible, be avoided.
Diclofenac has been found in the milk of nursing mothers. As with other drugs those are excreted in milk, diclofenac is not recommended for use in nursing women.

4.7 Effects on Ability to Drive and Use Machines

Not known

4.8 Undesirable Effects

At recommended doses, Soludol is generally well tolerated. However, with diclofenac, the following side effects have been reported, such as epigastric pain, nausea, diarrhea, dizziness or headache. These unwanted effects are usually of a mild nature.

The following side effects have seldom been reported with diclofenac although they have been observed in response to other non-steroidal, anti-inflammatory drugs. Peripheral oedema and skin reactions, such as drug rash, urticaria and eczema. Central nervous systems side effects, such as tiredness, insomnia and irritability, have occurred in rare instances. There have been a few reports of gastro-intestinal ulceration or haemorrhage, hypersensitivity reactions
(e.g. bronchospasm, anaphylactoid reactions), elevated transaminase levels, hepatitis, renal failure and nephritic syndrome, isolated cases of leucopenia and thrombocytopenia have also been observed.

5. Pharmacological Properties

5.1 Mode of Action

Soludol Dispersible Tablets contains diclofenac free acid, a non-steroidal, anti-inflammatory drug (NSAID). In pharmacological studies, diclofenac has shown anti-inflammatory, analgesic and antipyretic activity. As with other NSAIDs, its mode of action is not known, its ability to inhibit prostaglandin synthesis, however, may be involved in its anti-inflammatory activity, as well as contribute to its efficacy in relieving pain related to inflammation. With regards to its analgesic effect, diclofenac is not a narcotic.

In rheumatic disease, the anti-inflammatory and analgesic properties of Diclomol EC elicit a clinical response such as pain at rest or on movement, morning stiffness and swelling of the joints, as well as by an improvement of joint function.

5.2 Pharmacokinetic Properties

Diclofenac is well absorbed after oral administration and peak plasma levels are usually attained in 2-3 hours. Absorption occurs more rapidly when ingested on an empty stomach than when administered during or after a meal. Plasma concentrations show a linear relationship to the size of the dose administered. However, concentrations are maintained at higher levels in the synovial fluid than in plasma.
A large proportion of diclofenac is metabolized in the liver and about 30% of the ingested dose undergoes first pass metabolism. Approximately 65% of the dose is excreted in the urine, and approximately 35% in the bile.

Plasma concentration of diclofenac declines from peak levels in a biexponential fashion, with the terminal phase having a half-life of approximately 2 hrs. However, the elimination half-life from the synovial fluid is about three times longer than that from plasma.

Pharmacokinetic behavior remains unchanged following repeated administration. No accumulation occurs provided the recommended dosage intervals are observed.

No relevant age-dependent differences in the drug's absorption, metabolism, or excretion have been observed.

More than 99% is protein bound.

5.3 Pre-Clinical Safety Data

Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

S.No.	Name of the Excipients
1.	Croscarmellose Sodium (Ac-Di-Sol)
2.	Colloidal Anhydrous Silica (Aerosil-200)
3.	Hydrogenated Castor Oil (Cutina HR)
4.	Microcrystalline Cellulose (Avicel PH-101)
5.	Pineapple Flavour DC 106 PH(Dry)
6.	Sodium Saccharin
7.	Sodium Starch Glycollate
8	Talc
9	Tartrazine Yellow Lake

6.2 Incompatibilities

None Reported

6.3 Shelf life

36 months from the date of manufacturing

6.4 Special Precautions for Storage

Store protected from light and moisture at a temperature not exceeding 30°C

6.5 Nature and Content of Container

Soludol tablets are packed in printed aluminium foil (width 165 mm × thickness 0.03 mm) and plain aluminium foil (width 165 mm × thickness 0.03 mm).
Strips of 10's; Box of 10x10's

6.6 Instructions for use/handling

Not Applicable

7. Marketing Authorization Holder

Win-Medicare Pvt. Ltd.
1311, Modi Tower
98, Nehru Place
New Delhi – 110019, India.

8. Marketing Authorization Number

Fresh Registration

9. Date of first Authorization/Renewal of the Authorization

Fresh Registration

10. Date of Revision of the Text

April 2022