

SUMMARY OF PRODUCT CHARACTERISTICS

GVSOFT 1.2

(Glycerin Suppositories USP)

1. Name of the medicinal product

GVSOFT 1.2 (Glycerin Suppositories USP)

2. Qualitative and quantitative composition

Each suppository contains:

Glycerin USP.....1.2 g

Excipient.....q.s.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Rectal Suppository

4. Clinical particulars

4.1 Therapeutic indications

For the relief of occasional constipation.

4.2 Posology and method of administration

Children 2 to under 6 years carefully insert 1 suppository well into the rectum and retain for 15 minutes; it need not melt to produce laxative action. Do not exceed 1 suppository daily or as directed by a doctor.

Children under 2 years: Ask a doctor

Insert suppository well up to the rectum. To produce laxative action suppository is designed to dissolve only partially, which may not be noticeable.

4.3 Contraindications

Patients with known hypersensitivity to glycerin. The product is contraindicated if there is intestinal obstruction or blockage.

4.4 Special warnings and precautions for use

Caution should be taken in patients with intestinal obstruction or blockage.

Prolonged use of the product can precipitate onset of an atonic non-functioning colon.

Not to be taken orally. For rectal administration only.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No special precautions are considered necessary. Use only under a doctor's instruction in these conditions.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

When using this product your child may have rectal discomfort or a burning sensation.

May cause irritation and occasionally abdominal cramps, swelling and loose stools.

4.9 Overdose

Over dosage via rectal route is unlikely. However, if ingested treat symptomatically.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Glycerin is commonly classified as an osmotic laxative but may act additionally or alternatively by promoting peristalsis and evacuation of the lower bowel by virtue of a mild irritant effect. Glycerin suppositories possess also lubricating and faecal softening actions. Glycerin exerts a hyperosmotic laxative effect by attracting water into the rectum, thereby relieving constipation.

5.2 Pharmacokinetic properties

Glycerin is readily absorbed from the intestine and undergoes extensive metabolism principally in the liver, it may be used in the synthesis of lipid, metabolized to glucose or glycogen, or oxidized to carbon dioxide and water. It may also be excreted in the urine unchanged.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Stearate, Purified water.

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in dry place, below 30°C, protect from light.

6.5 Nature and contents of container

Finished product is packed in Aluminium/Polyethylene Foil. 2 Strips of 5 suppositories is packed in carton along with pack insert.

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorization holder

Bliss GVS Pharma Ltd.

102, Hyde Park, Saki-Vihar Road, Andheri (East), Mumbai – 400072.