

04-01-2023 2nd Copy



Trimethylphloroglucinol

For I.M / I.V. use

QUALITATIVE AND QUANTITATIVE COMPOSITION

Orglu® Injection

Each 4ml contains:

Phloroglucinol hydrate Ph. Eur. 40mg

Trimethylphloroglucinol MS......0.04mg

PHARMACEUTICAL FORM

Liquid Injection

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS:

Orglu® is indicated for the symptomatic treatment of:

- Colics due to renal or biliary calculi
- Acute pain due to spasm of bile ducts urinary passages or in gastrointestinal tracts
- Pain of uncertain genesis in the abdominal region
- Spastic conditions of the female genital system like dysmenorrhoea. Help to relieve the cervical spasm and facilitate cervical dilatation.

POSOLOGY AND METHOD OF ADMINISTRATION

-3 ampoules daily I.M./ I.V. or as directed by the physician.

CONTRAINDICATIONS

Hypersensitivity to phloroglucinol hydrate or trimethylphloroglucinol.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Org I u® should not be administered concomitantly with major analgesics such as morphine or morphine derivatives due to their spasmogenic effects.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Org I u[®] injection must not be mixed in the same syringe with noramidopyrine because of physio chemical incompatibility (risk of thrombophlebitis).

FERTILITY, PREGNANCY AND LACTATION

 ${
m Orglu^{\otimes}}$ should be taken during pregnancy only if necessary. Women who are breastfeeding should not take ${
m Orglu^{\otimes}}$.

UNDESIRABLE EFFECTS

As with other antispasmodics, Org I u[®]may cause troublesome side effects of varying degree in certain individuals. Allergic skin reactions have rarely been reported.

OVERDOSE:

No data available

PHARMACOLOGICAL PROPERTIES:

PHARMACODYNAMIC PROPERTIES:

Therapeutic classification: Musculotropic Antispasmodic.

ATC Code: A03AX12

Phloroglucinol relieves smooth muscle fiber spasm and relieves pain. It has antispasmodic effect on smooth muscles of the gastrointestinal, biliary and urogenital tracts

SHELF LIFE

See expiry on the pack

AVAILABILITY

Org I u[®]Injection in a pack of 6's

INSTRUCTIONS

Dosage: As directed by the physician.

To be sold on the prescription of a registered medical practitioner only.

Keep out of the reach of children.

Do not store over 30°C, and protect from heat, light and freezing.

Improper storage may deteriorate the medicine

Injection should not be used if container is leaking, solution is cloudy or it contains undissolved particle(s)

The labelled expiry date is valid only for an intact and correctly stored product. The prolonged storage of $OrgIu^{@}$ ampoules in cold environment can cause crystals to form which completely disappear when the ampoule is shaken for two minutes in hot water (Not more than 45°C). This phenomenon, as well as a slight yellowing of the ampoules, do not prejudice either the product activity or its harmlessness.

خوراک: ڈاکٹر کی ہدایت کےمطابق استعال کریں۔ مرف رجٹر ڈ ڈاکٹر کے نننج کےمطابق فروخت کریں۔ بچوں کی پہنچ ہے دورر کھیں۔

واکو ۳۰ ڈگری سنٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکیس، کری، روشنی اور نجمد ہونے ہے محفوظ کھیں ورنہ دواخراب ہوجائیگی۔

انجکشن کےلیک ہونے ، وُ هندلا ہونے یااس میں کوئی غیر حل پزیرشے نظر آنے کی صورت میں ہر گزاستعال نہ کریں۔

R.N-03/NA/01/2023

Manufactured by: SAMI Pharmaceuticals (Pvt.) Ltd. F-95, S.I.T.E., Karachi-Pakistan www.samipharmapk.com Mfg. Lic. No. 000072

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