Orglu® Tablets

(Phloroglucinol + Trimethylphloroglucinol)

COMPOSITION

Orglu® Tablets:
Each sugar coated tablet contains:
Phloroglucinol hydrate Ph. Eur.....80mg
Trimethylphloroglucinol MS.....80mg

DRUG DESCRIPTION

Orglu® tablets contain phloroglucinol which belongs to the class of organic compounds. These are compounds containing a phloroglucinol (benzene-1,3,5-triol) moiety. Phloroglucinol is musculotropic antispasmodic. Molecular formula is $C_6H_6O_3$.

CLINICAL PHARMACOLOGY

PHARMACODYNAMICS:
Pharmacotherapeutic group: Other drugs for functional bowel disorders
ATC Code: A03AX12
Mechanism of action: Phloroglucinol is a phenol derivative with antispasmodic properties. The mechanism of action is most likely based on the direct inhibition of the voltage-dependent calcium channels of smooth muscle; however, the modulation of prostaglandin or nitric oxide release has also been suggested.

PHARMACOKINETICS:
Information regarding the pharmacokinetics of Orglu® tablets is not available.

INDICATIONS AND DOSAGE

INDICATIONS AND USAGE:
Orglu® is indicated for:
- symptomatic treatment of pain related to functional disorders of digestive tract & bile ducts
- treatment of acute spasmodic painful disorders of urinary tract & renal colic
- symptomatic treatment of acute pain in gynaecology
- adjuvant treatment of contractions during pregnancy (in combination with rest)

DOSAGE AND ADMINISTRATION:
Method of administration:
Oral; it can be taken without regard to meal. The tablets should be swallowed whole with a glass of water.
Dosage:
The usual dose is 6 coated tablets per 24 hours; one to two tablets of Orglu® per dose, spaced 6 to 8 hours.
Missed dose: In case if dose is missed, patient should not be advised to take double dose to make up for the missed dose.

SPECIAL POPULATIONS:
Paediatric population: This presentation is not suitable for children under 6 years of age.
For children over 6 years of age: 1 tablet per dose, twice daily, with a minimum interval of 2 hours between each dose without exceeding 2 tablets per 24 hours. In children over 6 years old, it should be ensured that the tablets can be swallowed, otherwise another form will be preferred.
Geriatric population: No information is available.
Renal impairment: No information is available.
Hepatic impairment: No information is available.

OVERDOSAGE

Information regarding the over dosage of Orglu® tablets is not available.

CONTRAINDICATIONS

Orglu® tablets are contraindicated in individuals with a history of hypersensitivity to this product or any of its components.

WARNINGS AND PRECAUTIONS

CONCERNS RELATED TO ADVERSE EFFECTS:
Rare metabolic diseases: Due to the presence of sucrose, this drug should not be used in case of fructose intolerance, glucose-galactose malabsorption syndrome or sucrase-isomaltase deficiency.
Due to the presence of lactose, this drug should not be used in case of galactosemia, glucose-galactose malabsorption syndrome or lactase deficiency.

DISEASE-RELATED CONCERNS:
Nephritic colic: In cases of nephritic colic, it is generally advisable to drink of water plenty between pain crises to avoid formation of calculations. However, during a crisis, fluid absorption should be limited so as not to increase pain.

CONCURRENT DRUG THERAPY ISSUES:
Drug-drug interactions: Orglu® tablets should not be used concomitantly with potent analgesics such as morphine or its derivatives.

SPECIAL POPULATIONS:
Pregnancy: The scientific data currently available have not revealed any particular problem when using this medication during pregnancy at the recommended dose. The use of this medication should only be considered during pregnancy if necessary.
Lactation: The available data do not indicate whether this drug passes into breast milk: it is not recommended during breastfeeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
Orglu® has negligible effect on the ability to drive and use machines.

ADVERSE REACTIONS

The adverse reactions observed with Orglu® tablets include skin, subcutaneous & allergic reactions, including rash, rarely urticaria, exceptional angioedema, hypotension, anaphylactic shock.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:
Data not available.

REPORTING OF SUSPECTED ADVERSE REACTIONS:
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals and patients/carers are asked to report any suspected adverse reactions at safety@samikhi.com or call on +92 (0) 21 34383400 (Office hours and out of office hours). Also, adverse event may be reported via website: www.samipharmapk.com

DRUG INTERACTIONS

No interactions with other drugs are documented for Orglu® tablets. However, it should not be used concomitantly with potent analgesics such as morphine or its derivatives.

SHELF LIFE

See expiry on the pack.

AVAILABILITY

Orglu® tablets in a pack of 30's

INSTRUCTIONS

Dosage: As advised by the physician.
To be sold on the prescription of registered medical practitioner only.
Keep out of the reach of children.
Avoid exposure to heat, light and humidity.
Store between 15 to 30°C.
Improper storage may deteriorate the medicine.

اورگلو® ٹیبلٹ

(فلوروگلوسینول+ٹرائی میتھائل فلوروگلوسینول)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔

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