

170.00 mm

Tablet / Injection  
**SPAXATE**  
(Phloroglucinol dihydrate  
Trimethyl phloroglucinol)

سپاکسیز پ  
ٹیبلیٹ / انجکشن  
(فلورگلوکینول ڈائی ہائیڈریٹ  
ٹری میٹھیل فلورگلوکینول)

**COMPOSITION**

**Spaxate Tablet 80mg / 80mg**  
Each sugar coated tablet contains:  
Phloroglucinol dihydrate..... 80mg  
Trimethyl phloroglucinol..... 80mg  
(Innovator's Specifications)

**Spaxate Injection**

Each 4ml ampoule contains:  
Phloroglucinol Hydrate..... 40mg  
Trimethyl phloroglucinol..... 0.04mg  
(Innovator's Specifications)

**DESCRIPTION**

Phloroglucinol is a musculotropic antispasmodic agent to treat colic, as well as spastic pain of the digestive and biliary tracts.

**INDICATIONS**

- ▶ Symptomatic treatment of pain related to functional disorders of the gastrointestinal tract and biliary tract.
- ▶ Treatment of spasm and acute pain of the urinary tract: renal colic.
- ▶ Symptomatic treatment of painful spasm in gynaecology.
- ▶ Adjuvant therapy for contractions during pregnancy, in combination with rest.

**MECHANISM OF ACTION**

Phloroglucinol and trimethyl phloroglucinol have spasmolytic activity on smooth muscles and a visceral antinoceptive effect, particularly during episodes of acute pain.

**DOSAGE & ADMINISTRATION****For Injection**

**Initial treatment:** 1-3 ampoules per 24 hours by intravenous or intramuscular injection.

**Maintenance treatment:** Tablets should be used following initial treatment at the dosage of 6 tablets per 24 hours.

**Route of administration:** For Intravenous or Intramuscular Injection.

**For Tablet****In adults**

The usual dosage is 2 tablets per dose, three times a day, respecting a minimum interval of 2 hours between each dose, without exceeding 6 tablets per 24 hours.

The tablets can be used as a follow-up to an initial treatment by injection.

**Pediatric population**

This presentation is not suitable for children under 6 years old.

The usual dosage is one coated tablet per dose, twice a day, respecting a minimum interval of 2 hours between each dose, without exceeding 2 tablets per 24 hours.

In children over 6 years of age, it will be necessary to ensure that the tablets can be swallowed.

**PHARMACOKINETICS****Absorption**

After oral administration, peak plasma levels are reached between 40 and 60 minutes.

**Distribution**

Tissue distribution of phloroglucinol is rapid and extensive.

**Biotransformation**

Phloroglucinol is metabolized in the liver by glucuronidation.

**Elimination**

Elimination occurs via the urine in glucuroconjugated form and via the biliary tract in free and conjugated form. The elimination half-life is around 1 hour 40 minutes.

**WARNINGS & PRECAUTIONS**

- ▶ The combination of phloroglucinol with major analgesics such as morphine or its derivatives should be avoided due to their spasmogenic effect.
- ▶ Because of the presence of sucrose, this medicine must not be used in patients with fructose intolerance, glucose- galactose malabsorption syndrome or sucrose-isomaltase insufficiency (rare metabolic diseases).

- ▶ Because of the presence of lactose, this medicine must not be used in patients with galactosemia, glucose- galactose malabsorption syndrome or lactase deficiency (rare metabolic diseases).

**Pregnancy**

In clinical practice, the relatively widespread use of phloroglucinol has apparently revealed no malformative risk to date. However, epidemiological studies are necessary to verify the absence of risk. Therefore, the use of phloroglucinol should only be considered during pregnancy if clearly necessary.

**Breastfeeding**

In the absence of data, it is advisable to avoid the use of this medicine during breastfeeding.

**DRUG INTERACTIONS**

Phloroglucinol solution for injection must not be mixed in the same syringe with noramidopyrine because of physico-chemical incompatibility mainly the risk of thrombophlebitis.

In order to avoid possible interactions between several medicines, you should always inform your doctor or pharmacist of any type of treatment that you might be taking.

**SIDE EFFECTS**

Cutaneous, mucosal and allergic manifestations such as rash, rarely urticaria, very occasionally angioedema, hypotension, anaphylactic shock.

**CONTRAINDICATIONS**

Hypersensitivity or allergy to the active substance or to any of the excipients.

Spaxate tablet is contraindicated in patients with wheat allergy (other than coeliac disease).

**STORAGE & INSTRUCTIONS**

**Inj:** Store below 30°C.

**Tab:** Store below 25°C.

Protect from heat, sunlight and moisture.

Keep away from the reach of the children.

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

**HOW SUPPLIED**

**Spaxate Tablet 80mg / 80mg**

30 Tablets

**Spaxate Injection**

4ml x 10 ampoules

خوراک و طریقہ استعمال:  
ڈاکٹر کی ہدایت کے مطابق استعمال کریں

ہدایات:

ٹیبلیٹ: دو کو ۳ ڈگری سینٹی گریڈ سے کم درجہ حرارت میں رکھیں۔

انجکشن: دو کو ۳ ڈگری سینٹی گریڈ سے کم درجہ حرارت میں رکھیں۔

دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:

**PHARMASOL  
PRIVATE LIMITED**

Plot # 549, Sundar Industrial Estate,  
Lahore, Pakistan.

140.00 mm