

**INSTRUCTION
for medical use**

COLLICKID®

Composition:

active substance: simethicone;

1 tablet contains simethicone 125 mg;

excipients: magnesium-aluminum silicate, lactose monohydrate, microcrystalline cellulose, calcium hydrogen phosphate, stearic acid, silica colloidal anhydrous, crospovidone, povidone K 29/32, Opadry II 85G 52 218 yellow.

Pharmaceutical form. Coated tablets.

Basic physico-chemical properties: oval, smooth on both sides, yellow coated tablets.

Pharmacotherapeutic group.

Other drugs for functional gastrointestinal disorders. Silicones.

ATC code A03A X13.

Pharmacological properties.

Pharmacodynamics.

Simethicone, ingredient of the drug, is a non-toxic inert surface-active agent, made of silicon, it is a defoamer. It changes the surface tension of the gas bubbles formed in the intestines and causes their destruction. Gases, released during this, can be both absorbed by intestine wall and excreted from the organism due to peristalsis of intestine. The use of simethicone before diagnostic studies of the abdomen prevents image defects that are caused by gas bubbles; it promotes thorough irrigation of the of mucous coat of large intestine by contrast material that prevents contrasting film rupture even in case of intestine bloating.

Pharmacokinetics.

Simethicone acts only on the surface of the bubbles and is not absorbed by the mucous membrane of the digestive tract. Simethicone is not absorbed by the mucous membrane of the digestive tract and is excreted intact after oral usage. Simethicone does not have central action.

Clinical particulars.

Indications.

- Symptomatic treatment of the gastrointestinal tract disorders associated with flatus, such as flatulence, including in the postoperative period.
- As an adjunct during diagnostic examination of abdominal cavity organs (X-ray examination, ultrasound examination) and preparation for gastroduodenoscopy.
- As defoamer in intoxication with surface-active agents (washing powders or other detergents).

Contraindications.

- Hypersensitivity to the drug or its components.
- Intestinal obstruction.
- Obstructive diseases of the gastrointestinal tract.

Interaction with other medicinal products or other forms of interaction.

Concomitant use of simethicone with laxatives containing mineral oil (paraffin) is not recommended, since mixing these substances reduces the efficacy of simethicone.

Levothyroxine may bind with simethicone. Intestinal absorption of levothyroxine may be violated in case of concomitant use with simethicone.

Special precautions.

If gastrointestinal tract symptoms (complaints) appear repeatedly or last more than 14 days or increase, seek medical attention.

The drug contains lactose. If a patient has known intolerance to some sugars, he should consult his physician before taking this medicinal product.

Use during pregnancy or breast feeding.

There are no clinical data on use of the drug Collickid® in pregnant women. Since the active ingredient is not absorbed in the mucous coat of the gastrointestinal tract, one should not expect any effect of the drug on the fetus or accumulation of the drug in the breast milk.

Use of the drug Collickid® during pregnancy or breast feeding is possible only if the expected benefit for the mother outweighs the potential risk for the fetus or child.

Effects on ability to drive and operate machinery.

Since simethicone is an inert substance which is not absorbed, the effect on driving or operating machinery is practically excluded.

Dosage and administration.

Collickid® tablets are to be used orally by adults and children over 12 years old. The use of the drug does not depend on meals.

Symptomatic treatment in case of complaints on the gastrointestinal tract: 1 tablet 3 times per day.

As an adjunct during diagnostic examination of abdominal cavity organs: 1 tablet 3 times per day one day before the examination and 1 more tablet in the morning on the day of examination.

As defoamer in intoxication with surface-active agents (washing powders or other detergents): the dosage depends on the severity of intoxication. The minimum recommended dose is 3 tablets.

The duration of treatment course is determined individually. If necessary, the drug may be taken for a long time.

Children.

Collickid® tablets are used in children over 12 years old.

Children less than 12 years old are prescribed the drug in liquid pharmaceutical forms.

Overdose.

Until now, the cases of overdose are unknown. Since simethicone is inert in chemical and physiological sense, intoxication is practically excluded. In case of using doses that are higher than recommended, contact your physician.

Adverse reactions.

Immune system: allergic reactions, hypersensitivity reactions such as pruritus, skin rash, urticaria, facial swelling, tongue swelling and difficulty breathing.

Gastrointestinal tract: nausea, constipation.

Shelf life.

3 years.

Storage conditions.

Store in the original package at the temperature not more than 25 °C.

Keep out of reach of children.

Package.

7 tablets are in a blister, 2 blisters are in a carton box.

15 tablets are in a blister; 1 or 2, or 4 blisters are in a carton box.

Conditions of supply.

Without prescription.

Manufacturer.

KUSUM PHARM LLC.

Address.

40020, Ukraine, Sumy region, Sumy, Skryabina Str., 54

or

Manufacturer.

LLC “GLADPHARM LLC”.

Address of manufacturer and manufacturing site.

40020, Ukraine, Sumy region, Sumy, Davydovskoho Hryhoriia Str., 54.

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