APPROVED The Order of Ministry of Health of Ukraine <u>04.08.2020</u> № <u>1789</u> Registration certificate № UA/10461/02/01

INSTRUCTION for medical use

COLLICKID®

Composition:

active substance: 1 ml of suspension contains simethicone emulsion equivalent to simethicone 40 mg;

excipients: polysorbate 80, carbomer, sodium saccharin, glycerol, sodium benzoate (E 211), raspberry flavour, sodium hydroxide, purified water.

Pharmaceutical form. Oral suspension.

Main physico-chemical properties: white suspension with a characteristic flavor.

Pharmacotherapeutic group.

Medications used in functional gastrointestinal disorders. Silicones. ATC Code A03A X13.

Pharmacological properties.

Pharmacodynamics.

Simethicone, which is part of the drug, is a non-toxic inert silicon-based surfactant and an antifoaming agent. It changes the surface tension of gastrointestinal gas bubbles causing their collapse. The gases thus released may be both absorbed through the intestinal walls and eliminated by intestinal peristalsis. Simethicone administration prior to diagnostic examination of digestive tract organs prevents image defects caused by gas bubbles; it promotes thorough irrigation of the colon mucosa with the contrast agent, which prevents rupture of the contrast film even in case of intestinal distention.

Pharmacokinetics.

Simethicone acts only on the surface of the gas bubbles and is not absorbed by the digestive tract mucous membrane. Simethicone is not absorbed from the digestive tract mucosa and is excreted unchanged following oral administration. Simethicone doesn't provide central action.

Clinical characteristics.

Indications.

- Symptomatic treatment of gastrointestinal tract disorders associated with gas formation (e.g. flatulence, including during the postoperative period, infantile colic).
- As an adjunct during diagnostic examination of digestive tract organs (X-ray examination, ultrasound investigation) and preparation for gastroduodenoscopy.
- As an antifoaming agent in case of surfactant intoxication (washing powder or other detergents).

Contraindications.

- Hypersensitivity to the drug and its components.
- Intestinal obstruction.
- Obstructive diseases of the digestive tract.

Interaction with other medicinal products and other forms of interaction.

Simultaneous use of simethicone and laxatives containing mineral oil (paraffin) is not recommended, as mixing of these substances leads to a decrease in the effectiveness of simethicone.

Levothyroxine may bind to simethicone. Intestinal absorption of levothyroxine may be impaired in case of simultaneous administration with simethicone.

Administration details.

Medical advice should be sought if gastrointestinal symptoms (complaints) recur or last for more than 14 days or become more severe.

The medicinal product should be used with caution in patients with obstructive gastrointestinal diseases.

Use during pregnancy or breastfeeding.

Clinical data on the use of the drug Collickid[®] by pregnant women are not available. As the active ingredient is not absorbed by the gastrointestinal mucosa, no effect of the medicine on the fetus or accumulation of the medicine in breast milk should be expected.

Administration of the drug Collickid[®] during pregnancy or breastfeeding is possible only when the expected benefits for the mother exceed the potential risk for the fetus or child.

Effect on reaction rate when driving motor transport or using other mechanisms.

Since simethicone is an inert, non-absorbent substance, there is virtually no effect on driving or operating machinery.

Dosage and administration.

To ensure accurate dosing, the package contains a syringe dispenser. *Gastrointestinal tract disorders associated with gas formation*

| Age | Dosage | Frequency of administration |
|--|----------|--|
| Children under 1 year of age | 0,5–1 ml | Add Collickid [®] into the baby food bottle during each feeding or give before or after breastfeeding using a syringe dispenser |
| Children 1–6 years of age | 1 ml | The drug is administered during or after meals |
| Children 6–14 years of | 1–2 ml | every 4–6 hours |
| age | | |
| Children over 14 years of age and adults | 2 ml | |

Preparation for the diagnostic abdominal examination

|--|

| Age | Dosage and frequency of administration | | |
|----------|--|---------------------------|--|
| | The day before the | In the morning before the | |
| | examination | examination | |
| Children | 1 ml 3 times a day | 1 ml once | |
| Adults | 2 ml 3 times a day | 2 ml once | |

Preparation for gastroduodenoscopy

| Age | Dosage and frequency of administration | | |
|--------|--|--|--|
| | Before endoscopy | During endoscopy | |
| Adults | 4–8 ml once | If necessary, inject a few millilitres of the suspension through the endoscope channel to eliminate gas bubbles that interfere with the examination | |

As an antifoaming agent during intoxication with surfactants (depending on the severity of the poisoning)

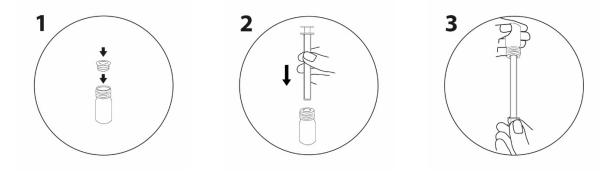
| Age | Dosage |
|----------|-------------------|
| Children | From 2.5 to 10 ml |
| Adults | From 10 to 20 ml |

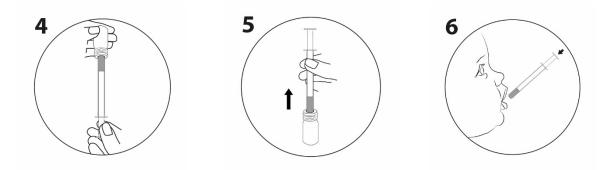
Collickid[®] can also be used during the postoperative period.

Method of administration of the oral suspension

- Shake the contents of the bottle well before opening.
- Insert the adapter for the syringe dispenser into the neck of the bottle when using for the first time (fig. 1).
- Insert the syringe dispenser into the adapter (fig. 2), flip the bottle upside down (fig. 3) and fill the syringe dispenser with the suspension by pulling the plunger to the graduation mark corresponding to the required amount of the drug in millilitres (ml) (fig. 4).
- Flip the bottle back right side up and remove the syringe dispenser from the adapter (fig. 5).
- Pour the contents of the syringe into the mouth (fig. 6).
- Close the bottle with the plastic cap, leaving the adapter in place.
- Rinse the syringe dispenser with water and dry it.

For children under 1 year of age, the suspension can be added to bottles with baby food.





The medicinal product is to be taken with or after meals, and if necessary, before sleep.

The duration of treatment depends on the presence of complaints and is determined by the physician individually.

If necessary, Collickid[®] can be used for a long time.

A clinical examination should be performed in case of recurrent and/or long-lasting digestive tract disorders.

Children.

The drug can be administered to children from birth.

Overdose.

No cases of overdose are known to date. Since simethicone is chemically and physiologically inert, intoxication is practically excluded. Consult a physician if doses higher than the recommended ones are used.

Adverse reactions.

Immune system disorders: allergic reactions, hypersensitivity reactions including pruritus, skin rash, urticaria, facial swelling, swelling of the tongue and difficulty breathing. *Gastrointestinal disorders:* nausea, constipation.

Shelf-life.

3 years.

Storage conditions.

Store in the original package at a temperature not more than 25 °C. Keep out of reach of children. After first opening the bottle, the drug should be stored for no more than 6 months.

Package.

30 ml of suspension are in a glass bottle. Each bottle is in a carton box with a 5 ml syringe dispenser and syringe adapter.

Conditions of supply.

Without prescription.

Manufacturer. LLC "KUSUM PHARM".

Address of manufacturer and manufacturing site. 40020, Ukraine, Sumy region, Sumy, Skryabina Str. 54.

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