Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Onecid Suspension (Dried Aluminium Hydroxide and Magnesium Trisilicate Suspension)

2. Qualitative and quantitative composition

Each 5 ml contains:

Dried Aluminium Hydroxide BP	120mg
Magnesium Trisilicate BP	250mg
Excipients	q.s

Excipients with known effect: sorbitol

For full list of excipients see section 6.1

3. Pharmaceutical form

Suspension for oral use 100ml.

Yellow viscous suspension with menthol and peppermint flavour free from any visible evidence of contamination.

4. Clinical particulars

4.1 Therapeutic indications

Onecid Suspension is an antacid. It is used to relieve the symptoms of indigestion, heartburn, or gastroesophageal reflux disorder (GERD).

4.2 Posology and method of administration

Oral.

RECOMMENDED DOSE

Adults and children over 12 years: two to four 5ml spoonfuls.

Children 5 to 12 years: one to two 5ml spoonfuls.

Directions for use: shake the bottle.

Take in a little water.

DOSAGE SCHEDULE

To be taken three times a day or as required

4.3 Contraindications

This combination is contraindicated for use:

- kidney problems as this may result in hypermagnesaemia (high blood levels of magnesium).
- bowel, intestinal, or stomach disease
- constipation
- diarrhea
- kidney disease
- liver disease
- on a sodium (salt) restricted diet
- stomach bleeding or obstruction

- an unusual or allergic reaction to aluminum hydroxide, magnesium trisilicate or other antacids, foods, dyes, or preservatives
- Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Aluminium hydroxide may cause constipation and magnesium salts overdose may cause hypomotility of the bowel; large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at higher risk such as those with renal impairment, or the elderly.

Aluminium hydroxide is not well absorbed from the gastrointestinal tract, and systemic effects are therefore rare in patients with normal renal function. However, excessive doses or long-term use, or even normal doses in patients with low-phosphorus diets may lead to phosphate depletion (due to aluminium-phosphate binding) accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia. Medical advice is recommended in case of long-term use or in patients at risk of phosphate depletion.

In patients with renal impairment, plasma levels of both aluminium and magnesium increase. In these patients, a long-term exposure to high doses of aluminium and magnesium salts may lead to dementia, microcytic anemia.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids may interact with a number of other drugs by altering their absorption and, sometimes, their elimination, thereby reducing their effectiveness. Antacids may also damage enteric coatings designed to prevent dissolution in the stomach. In order to minimise the risk of interactions, this product should not be taken within two to four hours of other medications (allow at least 4 hours before or 2 hours after erlotinib)

Check with your doctor or pharmacist before taking these **ONECID SUSPENSION** if you are taking any other medicines, including any that you can buy without a prescription. This is especially important if you are taking.

- the following medicines to treat infections: ciprofloxacin, pivampicillin, rifampicin, medicines called tetracyclines e.g. oxytetracycline, itraconazole or ketoconazole
- flecainide or mexiletine (to treat irregular heartbeat)
- quinine, chloroquine or hydroxychloroquine (to treat malaria)
- phenothiazines e.g. chlorpromazine, pericyazine (to treat schizophrenia and other mental disorders)
- phenytoin (to treat epilepsy)

- oral iron e.g. ferrous sulphate (to treat iron-deficiency anaemia)
- penicillamine (to treat severe rheumatoid arthritis)
- diflunisal or aspirin (painkillers)
- sucralfate (to treat stomach ulcers).
- methenamine
- uinidine
- rosuvastatin
- sotalol
- tacrolimus
- thyroid hormones like levothyroxine

Antacids since they inhibit the absorption of vitamins and should not be taken concomitantly.

- vitamin D

4.6 Pregnancy and Lactation

Pregnant Women

Aluminium hydroxide

Aluminium hydroxide has not been formally assigned to a pregnancy category. There are no controlled data in human pregnancy. Aluminium hydroxide is only recommended for use during pregnancy when benefit outweighs risk. Also there are no data on the excretion of aluminium hydroxide into human milk. Consult your physician before taking this drug

Magnesium Trisilicate

As there is no specific data for this product, it is recommended that Magnesium Trisilicate only be used in pregnancy on the advice of a doctor.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Feeling or being sick, constipation and diarrhoea, allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue bone or joint aches and pains confusion or irritability have been reported.

Patients who have kidney problems may experience hypermagnesaemia (an abnormally high level of magnesium in the blood). Symptoms may include flushing of the skin, thirst, low blood pressure, drowsiness, confusion, loss of tendon reflexes, muscle weakness, breathing difficulties, irregular heart beat, coma and cardiac arrest (heart stops pumping blood around the body).

Patients taking large doses of this medicine, or those with low phosphate diets taking normal doses, may experience problems with the levels of phosphate and calcium in their bodies. This may increase the risk of softening of the bones (osteomalacia).

Kidney stones may occur if the tablets are taken for a long time by patients who have kidney problems. If you have a kidney stone the main symptom is severe pain felt in the belly area or side of the back which may move to the groin area or the testicles. Other symptoms include unusual urine colour, blood in the urine, chills, fever, feeling or being sick.

Reporting of suspected adverse reactions:

Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS)
https://pv.pharmacyboardkenya.org

4.9 Overdose

Dried Aluminium Hydroxide

Serious symptoms are unlikely following overdosage. Reported symptoms of acute overdose with aluminium hydroxide salt include diarrhoea, abdominal pain, vomiting. Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk Aluminium eliminated through urinary route; treatment of acute overdose consists of administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.

Magnesium Trisilicate

Overdose, or excessive or prolonged intake of magnesium containing antacids may give rise to hypermagnesaemia
Symptoms of hypermagnesaemia include nausea, vomiting, flushing of the skin, thirst, drowsiness, hypotension, confusion, muscle weakness, CNS and respiratory depression, hyporeflexia, peripheral vasodilatation, bradycardia, cardiac arrhythmias, coma and cardiac arrest

5. Pharmacological properties

5.1 Pharmacodynamic properties

Dried aluminium hydroxide

Dried aluminium hydroxide - antacid
Aluminium hydroxide acts by neutralizing hydrochloric acid secreted by gastric parietal cells. Antacids such as aluminium hydroxide, being relatively insoluble in water, are long- acting if retained in the stomach. Aluminium decreases the intestinal motility; thus antacids containing aluminium tend to be constipating

Magnesium trisilicate

Magnesium trisilicate works by increasing the pH of gastric juice via a neutralisation reaction. It also precipitates colloidal silica, which can coat gastrointestinal mucosa conferring further protection. Magnesium trisilicate is an antacid with slow neutralising action and mild laxative action.

5.2 Pharmacokinetic properties

Dried aluminium hydroxide

Aluminium salts given my mouth, slowly reacts with the hydrochloric acid in the stomach to form soluble aluminium chloride, some of which is absorbed. The presence of food or other factors that decrease gastric emptying prolongs the availability of aluminium hydroxide to react and may increase the amount of aluminium chloride formed. Absorbed aluminium is eliminated in the urine, and patients with renal failure are therefore at particular risk of accumulation (especially in bone and the CNS), and aluminium toxicity. The aluminium compounds remaining in the GIT, which account for most of a dose, form insoluble, poorly absorbed aluminium salts in the intestines including hydroxides, carbonates, phosphates and fatty acid derivatives, which are excreted in the faeces.

Magnesium trisilicate

The gelatinous silicon dioxide, formed by the reaction of magnesium trisilicate with gastric contents is said to protect ulcerated mucosal surfaces and favor healing. The hydrated silicon dioxide formed in the stomach and passes into the intestinal track where, silica can be partly absorbed. And the rest is excreted in the urine

5.3 Preclinical safety data

None Known.

6. Pharmaceutical Particulars

6.1 List of Excipients

Sodium Methyl Paraben

Sodium Propyl Paraben

Tween 80

Sodium Citrate

Sorbitol

xanthan gum

Sodium Saccharin

Tartrazine colour

Peppermint Oil

Menthol Flavour

Rectified Spirit

purified water

6.2 Incompatibilities

None

6.3 Shelf-Life

36 Months

6.4 Special Precautions for storage

Store at a temperature not exceeding 30^0C. Protect from light.

6.5 Nature and Content of container

100 ml suspension packed in PET amber bottle affixed with coded label has batch number, manufacturing date and expiry date packed in unit box with an insert and 10 ml measuring cap.

6.6 Special precautions for disposal and other handling

None.

7. Marketing Authorization Holder

ZAIN PHARMA LIMITED

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8. Marketing Authorization Number

CTD9465

9. Date of first authorization/renewal of the authorization

06/10/2023

10. Date of revision of the text

11/05/2025