

**Size: 280 (L) x 420 (H) mm  
Folding size: 35 x 150 mm  
Drg. No. : 9918020-006  
Carton size: 43 x 36 x 85 mm**

**Front side**  
**Paper 35 to 45 gsm**

<div style="position: absolute; left: 0px; top: 0px; width: 100%; height: 100%; background-color: black; opacity: 0.

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**Back side**  
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280 mm

130 mm

150 mm

**PRECAUTIONS & WARNINGS:**

Other causes of frequent urination (heart failure or renal disease) should be assessed before treatment with Solifenacin. If urinary tract infection is present, an appropriate antibacterial therapy should be started.

Solifenacin should be used with caution in patients with:

- Clinically significant bladder outflow obstruction at risk of urinary retention.
- Gastrointestinal obstructive disorders.
- Risk of decreased gastrointestinal motility.
- Severe renal impairment (creatinine clearance  $\leq$  30 ml/min), and doses should not exceed 5 mg for these patients.
- Moderate hepatic impairment (Child-Pugh score of 7 to 9), and doses should not exceed 5 mg for these patients.
- concomitant use of a potent CYP3A4 inhibitor, e.g. ketoconazole
- Hiatus hernia/gastro-oesophageal reflux and/or who are concurrently taking medicinal products (such as bisphosphonates) that can cause or exacerbate oesophagitis.
- Autonomic neuropathy.

QT prolongation and Torsade de Pointes have been observed in patients with risk factors, such as pre-existing long QT syndrome and hypokalaemia.

Safety and efficacy have not yet been established in patients with a neurogenic cause for detrusor overactivity.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

Angioedema with airway obstruction has been reported in some patients on solifenacin succinate. If angioedema occurs, solifenacin succinate should be discontinued and appropriate therapy and/or measures should be taken.

Anaphylactic reaction has been reported in some patients treated with solifenacin succinate. In patients who develop anaphylactic reactions, solifenacin succinate should be discontinued and appropriate therapy and/or measures should be taken.

The maximum effect of Solifenacin can be determined after 4 weeks at the earliest.

**Effects on ability to drive and use machines:**

Since solifenacin, like other anticholinergics may cause blurred vision, and, uncommonly, somnolence and fatigue, the ability to drive and use machines may be negatively affected.

**PREGNANCY AND LACTATION:**

**Pregnancy:**

No clinical data are available from women who became pregnant while taking solifenacin. Animal studies do not indicate direct harmful effects on fertility, embryonal / foetal development or parturition. The potential risk for humans is unknown. Caution should be exercised when prescribing to pregnant women.

**Lactation:**

No data on the excretion of solifenacin in human milk are available. In mice, solifenacin and/or its metabolites was excreted in milk, and caused a dose dependent failure to thrive in neonatal mice. The use of Solifenacin should therefore be avoided during breast-feeding.

**INTERACTIONS:**

**Pharmacological interactions**

Concomitant medication with other medicinal products with anticholinergic properties may result in more pronounced therapeutic effects and undesirable effects. An interval of approximately one week should be allowed after stopping treatment with Solifenacin, before commencing other anticholinergic therapy. The therapeutic effect of solifenacin may be reduced by concomitant administration of cholinergic receptor agonists. Solifenacin can reduce the effect of medicinal products that stimulate the motility of the gastro-intestinal tract, such as metoclopramide and cisapride.

**Pharmacokinetic interactions**

In vitro studies have demonstrated that at therapeutic concentrations, solifenacin does not inhibit CYP1A1/2, 2C9, 2C19, 2D6, or 3A4 derived from human liver microsomes. Therefore, solifenacin is unlikely to alter the clearance of drugs metabolised by these CYP enzymes.

Effect of other medicinal products on the pharmacokinetics of solifenacin

Solifenacin is metabolised by CYP3A4. Simultaneous administration of ketoconazole (200 mg/day), a potent CYP3A4 inhibitor, resulted in a two-fold increase of the AUC of solifenacin, while ketoconazole at a dose of 400 mg/day resulted in a three-fold increase of the AUC of solifenacin. Therefore, the maximum dose of Solifenacin should be restricted to 5 mg, when used simultaneously with ketoconazole or therapeutic doses of other potent CYP3A4 inhibitors (e.g. ritonavir, nelfinavir, itraconazole).

Simultaneous treatment of solifenacin and a potent CYP3A4 inhibitor is contra-indicated in patients with severe renal impairment or moderate hepatic impairment.

The effects of enzyme induction on the pharmacokinetics of solifenacin and its metabolites have not been studied as well as the effect of higher affinity CYP3A4 substrates on solifenacin exposure. Since solifenacin is metabolised by CYP3A4, pharmacokinetic interactions are possible with other CYP3A4 substrates with higher affinity (e.g. verapamil, diltiazem) and CYP3A4 inducers (e.g. rifampicin, phenytoin, and carbamazepine).

Effect of solifenacin on the pharmacokinetics of other medicinal products

**Oral Contraceptives**

Intake of Solifenacin showed no pharmacokinetic interaction of solifenacin on combined oral contraceptives (ethinylestradiol/levonorgestrel).

**Warfarin**

Intake of Solifenacin did not alter the pharmacokinetics of R-warfarin or S warfarin or their effect on prothrombin time.

**Digoxin**

Intake of Solifenacin showed no effect on the pharmacokinetics of digoxin.

**ADVERSE DRUG REACTIONS:**

**Summary of the safety profile**

Due to the pharmacological effect of solifenacin, Solifenacin may cause anticholinergic undesirable effects of (in general) mild or moderate severity. The frequency of anticholinergic undesirable effects is dose related.

The most commonly reported adverse reaction with Solifenacin was dry mouth. It occurred in 11% of patients treated with 5 mg once daily, in 22% of patients treated with 10 mg once daily and in 4% of placebo-treated patients. The severity of dry mouth was generally mild and did only occasionally lead to discontinuation of treatment. In general, medicinal product compliance was very high (approximately 99%) and approximately 90% of the patients treated with Solifenacin completed the full study period of 12 weeks treatment.

Tabulated list of adverse reactions

| MedDRA system organ class                            | Very common<br>$\geq 1/10$ | Common<br>$\geq 1/100, < 1/10$                        | Uncommon<br>$\geq 1/1000, < 1/100$                  | Rare<br>$\geq 1/10000, < 1/1000$                      | Very rare<br>$< 1/10,000$                        | Not known (cannot be estimated from the available data)   |
|--|----------------------------|---|---|---|--|---|
| Infections and infestations                          |                            |   | Urinary tract infection<br>Cystitis                 |   |  |   |
| Immune system disorders                              |                            |   |   |   |  | Anaphylactic reaction*  |
| Metabolism and nutrition disorders                   |                            |   |   |   |  | Decreased appetite*<br>Hyperkalaemia*   |
| Psychiatric disorders                                |                            |   |   |   | Hallucinations*<br>Confusional state*            | Delirium*   |
| Nervous system disorders                             |                            |   | Somnolence<br>Dysgeusia                             | Dizziness*, Headache*                                 |  |   |
| Eye disorders  |                            | Blurred vision  | Dry eyes  |   |  | Glaucoma*   |
| Cardiac disorders                                    |                            |   |   |   |  | Torsade de Pointes*<br>Electrocardiogram QT prolonged*<br>Atrial fibrillation*<br>Palpitations*<br>Tachycardia* |
| Respiratory, thoracic and mediastinal disorders      |                            |   | Nasal dryness                                       |   |  | Dysphonia*  |
| Gastrointestinal disorders                           | Dry mouth                  | Constipation<br>Nausea<br>Dyspepsia<br>Abdominal pain | Gastro-oesophageal reflux<br>diseases<br>Dry throat | Colonic obstruction<br>Faecal impaction,<br>Vomiting* |  | Ileus*<br>Abdominal discomfort*   |
| Hepatobiliary disorders                              |                            |   |   |   |  | Liver disorder*<br>Liver function test abnormal*  |
| Skin and subcutaneous tissue disorders               |                            |   | Dry skin  | Pruritus*, Rash*                                      | Erythema multiforme*,<br>Urticaria*, Angioedema* | Exfoliative dermatitis*   |
| Musculoskeletal and connective tissue disorders      |                            |   |   |   |  | Muscular weakness*  |
| Renal and urinary disorders                          |                            |   |   | Difficulty in micturition                             | Urinary retention                                | Renal impairment*   |
| General disorders and administration site conditions |                            |   |   | Fatigue Peripheral oedema                             |  |   |

\*observed post marketing

**OVERDOSEAGE AND TREATMENT:**

**Symptoms**

Over dosage with solifenacin succinate can potentially result in severe anticholinergic effects. The highest dose of solifenacin succinate accidentally given to a single patient was 280 mg in a 5 hour period, resulting in mental status changes not requiring hospitalization.

**Treatment**

In the event of overdose with solifenacin succinate the patient should be treated with activated charcoal. Gastric lavage is useful if performed within 1 hour, but vomiting should not be induced.

As for other Anticholinergics, symptoms can be treated as follows:

- Severe central anticholinergic effects such as hallucinations or pronounced excitation: treat with Physostigmine or charbachol.
- Convulsions or pronounced excitation: treat with benzodiazepines.
- Respiratory insufficiency: treat with artificial respiration.
- Tachycardia: treat with beta-blockers.
- Urinary retention: treat with catheterization.
- Mydriasis: treat with pilocarpine eye drops and/or place patient in dark room.

As with other antimuscarinics, in case of overdosing, specific attention should be paid to patients with known risk for QT-prolongation (i.e. hypokalaemia, bradycardia and concurrent administration of medicinal products known to prolong QT-interval) and relevant pre-existing cardiac diseases (i.e. myocardial ischaemia, arrhythmia, congestive heart failure).

**STORAGE CONDITION:** Store at temperatures not exceeding 30°C.

**DOSAGE FORMS AND PACKAGING AVAILABLE:**

Film-coated tablets

Alu/PVC Blister Pack of 10's (Box of 30's)

**INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE):** Not Applicable

**NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:**

**Marketing Authorization Holder**

Brown & Burk Philippines Inc  
U-501, 5/F., SEDCCO 1 Bldg., 120 Rada cor., Legaspi Sts., Legaspi Village, Makati City, Philippines

**NAME AND ADDRESS OF MANUFACTURER:**

**MICRO LABS LIMITED**  
92, SIPCOT, HOSUR-635 126,  
TAMIL NADU, INDIA.

**CAUTION STATEMENT: FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION .**

**ADR REPORTING STATEMENT:**

FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA: [www.fda.gov.ph](http://www.fda.gov.ph)

Seek medical attention immediately at the first sign of Adverse Drug Reaction.

**REGISTRATION NUMBER:**

URGISO 5 mg: DR-XY47877

URGISO 10 mg: DR-XY47876

**DATE OF FIRST AUTHORIZATION:**

URGISO 5 mg: 1 APRIL 2022

URGISO 10 mg: 1 APRIL 2022

**DATE OF REVISION OF PACKAGE INSERT:** April 2022

EXG-ML011-1808

PHARMACODE READING  
DIRECTION

| MICRO LABS LIMITED, BANGALORE, INDIA |                   |                      |                    |             |   |                   |
|--------------------------------------|-------------------|----------------------|--------------------|-------------|---|-------------------|
| 1                                    | Product Name      | Urgiso               |                    |             | Colours Used                              |                   |
| 2                                    | Strength          | 5 mg                 |                    |             | <input checked="" type="checkbox"/> BLACK |                   |
| 3                                    | Component         | Leaflet              |                    |             |   |                   |
| 4                                    | Category          | Export - Philippines |                    |             |   |                   |
| 5                                    | Dimension         | 280 (L) x 420 (H) mm |                    |             |   |                   |
| 6                                    | Artwork Code      | EXG-ML01I-1808       |                    |             |   |                   |
| 7                                    | Pharma Code       | 296                  |                    |             |   |                   |
| 8                                    | Reason for Change | New Artwork          |                    |             |   |                   |
|                                      |                   | Prepared by<br>(DTP) | Checked by<br>(PD) | Approved by |   |                   |
| Sign                                 | Kantharaju L.     |                      |                    | Head CQA    | Head Production/<br>Packing (Site)        | Head QC<br>(Site) |
| Sign                                 | Kantharaju L.     |                      |                    |             |   |                   |
| Date                                 | 14-11-2022        |                      |                    |             |   |                   |

14 (L) x 6 (H) mm



PHARMACODE READING

DIRECTION

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