

Bispec-5 & Bispec-10 Tablets

Consumer Medication Information Leaflet (RiMUP)

Solifenacin Succinate (5 mg and 10 mg)

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What Bispec is used for

Bispec is used to treat the symptoms of a condition called overactive bladder. These symptoms include having a strong, sudden urge to urinate without prior warning, having to urinate frequently or wetting yourself because you could not get to the bathroom in time.

How Bispec works

The active substance of Bispec belongs to the group of anticholinergics. These medicines are used to reduce the activity of an overactive bladder. This enables you to wait longer before having to go to the bathroom and increases the amount of urine that can be held by your bladder.

Before you take Bispec

- When you must not take it

Do not take Bispec:

- if you have an inability to pass water or to empty your bladder completely (urinary retention)
- if you have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis)
- if you suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles

- if you suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma)
- if you are allergic to solifenacin or any of the other ingredients of this medicine (listed in *Product Description*).
- if you are undergoing kidney dialysis
- if you have severe liver disease
- if you suffer from severe kidney disease or moderate liver disease AND at the same time are being treated with medicines that may decrease the removal of Bispec from the body (for example, ketoconazole). Your doctor or pharmacist will have informed you if this is the case.
- if you are pregnant or breast-feeding.

Inform your doctor if you have or ever had any of the above-mentioned conditions before treatment with Bispec starts.

Pregnancy and Breastfeeding

You should not use Bispec if you are pregnant unless clearly necessary.

Do not use Bispec if you are breastfeeding as Solifenacin may get into your breastmilk.

Ask your doctor or pharmacist for advice before taking this medicine.

- Before you start to take it

Talk to your doctor or pharmacist before taking Bispec:

- if you have trouble emptying your bladder (bladder obstruction) or have difficulty in passing urine (e.g. a thin urine flow). Risk of accumulation of urine in the bladder (urinary retention) is much higher.
- if you have some obstruction of the digestive system (constipation).
- if you are at risk of your digestive system slowing down (stomach and bowel movements). Your doctor will have informed you if this is the case.

- if you suffer from severe kidney disease.
- if you have moderate liver disease.
- if you have a stomach tear (hiatus hernia) or heartburn.
- if you have a nervous disorder (autonomic neuropathy).
- if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Children and Adolescents

Bispec is not to be used in children or adolescents under 18 years.

Inform your doctor if you have or ever had any of the above-mentioned conditions before treatment with Bispec starts.

Before starting Bispec, your doctor will assess whether there are other causes for your need to pass urine frequently (for example heart failure (insufficient pumping power of the heart) or kidney disease). If you have a urinary tract infection, your doctor will prescribe you an antibiotic (a treatment against particular bacterial infections).

- Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought without a prescription from a pharmacy, supermarket or health food shop.

It is especially important to inform your doctor if you are taking:

- other anticholinergic medicines, effects and side effects of both medications can be enhanced.
- cholinergics as they can reduce the effect of Bispec.
- Metoclopramide and Cisapride, which make the digestive system work faster. Bispec can reduce their effect.
- Ketoconazole, Ritonavir, Nelfinavir, Itraconazole, Verapamil and Diltiazem, which decrease the rate at

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which Bispec is broken down by the body

- Rifampicin, Phenytoin and Carbamazepine, as they may increase the rate at which Bispec is broken down by the body.
- Bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

How to take Bispec

- How much to take **Adults, including elderly**

The usual dose is 5 mg per day, unless your doctor told you to take 10 mg per day.

Pediatric population

The safety and efficacy of Solifenacin Succinate in children have not yet been established. Therefore, Solifenacin succinate should not be used in children.

Patients with renal impairment

No dose adjustment is necessary for patient with mild to moderate renal impairment (creatinine clearance > 30 mL/min). Patients with severe renal impairment (creatinine clearance ≤ 30 mL/min) should be treated with caution and receive not more than 5 mg once daily.

Patients with hepatic impairment

No dose adjustment is necessary for patients with mild hepatic impairment. Patients with moderate hepatic impairment (Child-Pugh score of 7 to 9) should be treated with caution and receive no more than 5 mg once daily.

Potent inhibitors of cytochrome P450 3A4

The maximum dose of Solifenacin succinate should be limited to 5 mg when treated simultaneously with Ketoconazole or therapeutic doses of other potent CYP3A4-inhibitors e.g. Ritonavir, Nelfinavir and Itraconazole.

- When to take it

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You should swallow the whole tablet with some liquid. Do not crush the tablets. It can be taken with or without food, according to your preference.

- How long to take it

If you stop taking Bispec, your symptoms of overactive bladder may return or worsen. Always consult your doctor, if you are considering stopping the treatment.

- If you forget to take Bispec

If you forget to take a dose at the usual time, take it as soon as you remember, unless it is time to take your next dose. Never take more than one dose per day. If you are in doubt, always consult your doctor or pharmacist.

- If you take too much (overdose)

If you have taken too much Bispec, contact your doctor or pharmacist immediately.

Symptoms of overdose may include: headache, dry mouth, dizziness, drowsiness and blurred vision, perceiving things that are not there (hallucinations), over-excitability, seizures (convulsions), difficulty breathing, elevated heart rate (tachycardia), accumulation of urine in the bladder (urinary retention) and dilated pupils (mydriasis).

While you are taking Bispec

- Things you must do

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Things you must not do

Do not stop taking Bispec or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Bispec to anyone else even if they have the same condition as you.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

- Things to be careful of **Driving and using machines**

Bispec may affect your ability to drive or use machines as it may cause blurred vision and sometimes sleepiness or tiredness. If you suffer from any of these side effects, do not drive or operate machinery.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Very common

- dry mouth

Common

- blurred vision
- constipation
- nausea
- indigestion with symptoms such as abdominal fullness, abdominal pain, burping, nausea, and heartburn (dyspepsia), stomach discomfort
- life-threatening allergic reaction
- decreased appetite
- hallucinations, confusion, rash
- dizziness
- headaches
- eye disorder
- changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat, faster heartbeat, voice disorder
- vomiting

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- liver disorder and liver function test abnormal
- red and itchy skin, hives
- accumulation of fluid in the lower legs
- muscle weakness
- renal impairment

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers ->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Bispec

- Storage

Keep this medicine out of the sight and reach of children.

Do not use Bispec after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

- Disposal

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product Description

- What it looks like

Bispec – 5

Light yellow colored, round, biconvex film coated tablets debossed with “C” and “259” on one side and plain on the other.

Bispec – 10

Light pink colored, round, biconvex film coated tablets debossed with “C” and “261” on one side and plain on the other.

- Ingredients

Active ingredient:

Solifenacin succinate

Inactive ingredient:

Bispec – 5

Microcrystalline cellulose (Avicel PH 101), colloidal silicon dioxide, hydroxy propyl methyl cellulose E-15 (HPMC E-15), purified water, hypromellose (HPMC-6 CPS), butyl hydroxy anisole, magnesium stearate, opadry yellow 03F520184.

Bispec – 10

Microcrystalline cellulose (Avicel PH 101), colloidal silicon dioxide, hydroxy propyl methyl cellulose E-15 (HPMC E-15), purified water, hypromellose (HPMC-6 CPS), butyl hydroxy anisole, magnesium stearate, opadry pink 03F540139.

- MAL Number

Bispec-5 MALXXXXXXXXX

Bispec-10 MALXXXXXXXXX

- Pack Size

1 x 10's

Manufacturer

CIPLA LTD.

S-103 to S-105, S-107 to S-112,
L-138, L-147, L-147/1 to L-147/3 & L-147/A, Verna Industrial Estate, Verna,
Goa 403 722 INDIA

Product Registration Holder

CIPLA MALAYSIA SDN BHD

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