

PATIENT INFORMATION LEAFLET

SPANOL® 40 mg film-coated tablet

It is taken orally.

- **Active substance:** 40 mg otilonium bromide
- **Excipients:** Lactose monohydrate of bovine origin, corn starch, sodium starch glycolate, magnesium stearate, hypromellose, titanium dioxide (E171), talc and polyethylene glycol.

Read this leaflet carefully before you start taking this medicine because it contains important information for you.

- *Keep these instructions for use. You may need to read it again later.*
- *If you have any further questions, please consult your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *During the use of this medicine, tell your doctor that you are taking this medicine when you go to the doctor or hospital.*
- *Follow these instructions exactly as written. Do not use a **higher or lower** dose than the recommended dose.*

This is in the instructions for use

1. What is SPANOL® and what is it used for?

2. Things to consider before using SPANOL ®

3. How to use SPANOL ®

4. What are the possible side effects?

5. Storage of SPANOL ®

1. What is SPANOL® and what is it used for?

SPANOL® contains otilonium bromide, which belongs to a group of medicines called "antispasmodics" (antispasmodics).

SPANOL® acts on the muscles in the digestive tract, relieves intestinal spasms and regulates excessive motility (such as controlling excessive contraction and speed of the intestinal muscles).

SPANOL® is used in irritable bowel syndrome and other digestive system conditions characterized by painful intestinal spasms, tension and movement problems.

SPANOL® is available in blister packs of 30 and 90 film-coated tablets. It is in the form of white, round film-coated tablets.

2. Things to consider before using SPANOL ®

DO NOT use SPANOL® in the following situations

If you do

- If you are allergic (hypersensitive) to otilonium bromide or any of the excipients contained in SPANOL ®
- If there is a colon obstruction

Use SPANOL® with Caution in the following situations

If you do;

- Glaucoma (an eye disease in which the pressure in the eyeball increases)
- If you have an enlarged prostate gland (also known as prostatic hypertrophy)
- If you have a narrowing in the canal passing from the stomach to the intestine (pyloric stenosis)
- If you suffer from constipation due to lazy bowel (atony) (e.g. due to diabetes): SPANOL® relaxes the muscles of the digestive tract. Therefore, use SPANOL® with caution if you suffer from constipation or lazy bowel (atony), which is more common in diabetics.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Use of SPANOL® with food and drink

Take SPANOL® preferably 20 minutes before meals.

Pregnancy

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

Do not use SPANOL® if you are pregnant unless your doctor has told you that it is necessary. In such cases, use under the supervision of your doctor.

If you notice that you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breastfeeding

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

Do not use SPASMOMEN if you are breastfeeding unless your doctor has told you that it is necessary. In such cases, use under the supervision of your doctor.

Vehicle and machine use

SPANOL® is not expected to affect the ability to drive and use machines.

Important information about some excipients contained in SPANOL ®

This medicine contains lactose from bovine origin. If you have been previously told by your doctor that you are intolerant to certain sugars, contact your doctor before taking this medicinal product.

This medicinal product contains less than 1 mmol (23 mg) sodium per film-coated tablet. No sodium-related side effects are expected at this dose.

Concomitant use with other medicines

No interaction has been reported in the use of SPANOL® with other medicines.

Please tell your doctor or pharmacist if you are currently taking or have recently taken any prescription or non-prescription medicines.

3. How to use SPANOL®

Instructions for appropriate use and dose/frequency of administration:

- Always use SPANOL® as recommended by your doctor. If you are unsure about anything, please consult your doctor or pharmacist.
- According to your doctor's advice: take 1 tablet 2-3 times a day.

Way and method of implementation:

- Take the tablets with a little water, without breaking, crushing or chewing, preferably 20 minutes before meals.

Different age groups:

Use in children and adolescents under 18 years of age:

The use of SPANOL® is not suitable for children and adolescents under 18 years of age.

Use in the elderly and adults:

According to your doctor's advice: take 1 tablet 2-3 times a day.

Special use cases:

Renal/liver failure:

No dose adjustment is required for SPANOL® in these patients.

If you have the impression that the effect of SPANOL® is too strong or too weak, talk to your doctor or pharmacist.

If you have used more SPANOL® than you should:

No overdose effects have been reported with SPANOL . ®

However, if you have taken more than you should and do not feel well, talk to your doctor or go to the nearest hospital and take the medicine box or this leaflet with you if possible

If you have used more SPANOL® than you should, talk to a doctor or pharmacist.

If you forget to take SPANOL® :

If you have forgotten to take a dose, take the next dose as soon as you remember.

Do not take a double dose to make up for forgotten doses.

Possible effects when treatment with SPANOL® is discontinued:

If you do not take your medicine as prescribed, you may not benefit from treatment. However, no side effects are expected if treatment is stopped early.

If you have more detailed questions about the use of the product, consult your doctor or pharmacist.

4. What are the possible side effects?

Like all medicines, side effects may occur in people sensitive to the ingredients of SPANOL®.

Side effects are listed according to the frequency classification below;

Very common : Occurs in at least one in 10 patients.

Widespread : Less than one in 10 patients, but more than one in 100 patients.

Uncommon: Less than one in 100 patients, but more than one in 1,000 patients.

Seyrek : Less than one in 1,000 patients, but more than one in 10,000 patients.

Very sparse : Less than one in 10,000 patients.

Unknown : The frequency cannot be estimated from the available data

IMMEDIATELY or contact the emergency department of the nearest hospital.

- Symptoms of an allergic reaction such as difficulty breathing or swallowing, swelling of the face, lips, tongue or throat, severe itching with rashes or bumps on the skin

These are all very serious side effects. If you have any of these, you are seriously allergic to SPANOL® . You may need urgent medical attention or hospitalization.

Uncommon

- Digestive disorders such as dry mouth, nausea and upper abdominal pain
- Itching and redness
- Fatigue and weakness
- Headache and vertigo (dizziness)

Isolated cases of skin sensitization reactions, such as rash (urticaria) and swelling of deeper layers of the skin, especially around the lips, eyes, genitals, hands, feet and throat or tongue, have been observed in patients taking this medicine. In some cases, sudden difficulty breathing (angioedema) is possible.

If you experience any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. Storage of SPANOL®

Keep SPANOL® out of the sight and reach of children and in its packaging.

Store at room temperature below 25 C. °

Use in accordance with the expiration date.

Do not use SPANOL® after the expiry date on the package.

Do not use SPANOL® if you notice any defects in the product and/or its packaging.

Do not throw expired or unused medicines in the garbage! Give them to the collection

Do not throw expired or unused medicines in the garbage! Give them to the collection system designated by the Ministry of Environment, Urbanization and Climate Change.

Marketing Authorization Holder:

Santa Farma İlaç San. A.Ş.

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This leaflet has been approved on .././.....