

Package leaflet: Information for the user
Pantoprazole 20 mg gastro-resistant tablets
Pantoprazole

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Pantoprazole 20 mg is and what it is used for
2. What you need to know before you take Pantoprazole 20 mg
3. How to take Pantoprazole 20 mg
4. Possible side effects
5. How to store Pantoprazole 20 mg
6. Contents of the pack and other information

1. What Pantoprazole 20mg is and what it is used for

Pantoprazole is a selective “proton pump inhibitor”, a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

Pantoprazole is used for:

Adults and adolescents 12 years of age and above:

- Treating symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease caused by reflux of acid from the stomach.
- Long-term management of reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitation of stomach acid) and preventing its return.

Adults:

- Preventing duodenal and stomach ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs, for example, ibuprofen) in patients at risk who need to take NSAIDs continuously.

2. What you need to know before you take Pantoprazole 20mg

Do not take Pantoprazole

- If you are allergic (hypersensitive) to pantoprazole or to any of the other ingredients of Pantoprazole (see section 6).
- If you are allergic to medicines containing other proton pump inhibitors.

Warnings and precautions

Take special care with Pantoprazole

- If you have severe liver problems. Please tell your doctor if you have ever had problems with your liver. He will check your liver enzymes more frequently, especially when you are taking Pantoprazole as long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.
- If you need to take medicines called NSAIDs continuously and receive Pantoprazole because you have an increased risk of developing stomach and intestinal complications. Any increased risk will be assessed according to your own personal risk factors such as your age (65 years old or more), a history of stomach or duodenal ulcers or of stomach or intestinal bleeding.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive pantoprazole long-term treatment. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking a medicine containing atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.

Taking a proton pump inhibitor like Pantoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis)

Tell your doctor immediately if you notice any of the following symptoms:

- an unintentional loss of weight
- repeated vomiting
- difficulty in swallowing
- vomiting blood
- you look pale and feel weak (anaemia)
- you notice blood in your stools
- severe and/or persistent diarrhoea, as Pantoprazole has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

If you take Pantoprazole on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Other medicines and Pantoprazole

Pantoprazole may influence the effectiveness of other medicines, so tell your doctor if you are taking

- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because Pantoprazole may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Atazanavir (used to treat HIV-infection).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. If you are pregnant, or think you may be pregnant, or if you are breast-feeding, you should use this medicine only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

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

Driving and using machines

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

3 How to take Pantoprazole 20mg

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

When and how should you take Pantoprazole ?

Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

Unless told otherwise by your doctor, the usual dose is:

Adults and adolescents 12 years of age and above:

To treat symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease

The usual dose is one tablet a day. This dose usually brings relief within 2 - 4 weeks – at most after another 4 weeks. Your doctor will tell you how long to continue taking the medicine. After this any recurring symptoms can be controlled by **taking one tablet daily**, when required.

For long-term management and for preventing the return of reflux oesophagitis

The usual dose is one tablet a day. If the illness returns, your doctor can double the dose, in which case you can use Pantoprazole 40 mg tablets instead, one a day. After healing, you can reduce the dose back again to one tablet 20 mg a day.

Adults:

To prevent duodenal and stomach ulcers in patients who need to take NSAIDs continuously

The usual dose is one tablet a day.

Special patient groups:

- If you suffer from severe liver problems, you should not take

- more than one 20 mg tablet a day.
- Children below 12 years. These tablets are not recommended for use in children below 12 years.

If you take more Pantoprazole than you should

Tell your doctor or pharmacist. There are no known symptoms of overdose.

If you forget to take Pantoprazole

Do not take a double dose to make up for the forgotten dose. Take your next normal dose at the usual time.

If you stop taking Pantoprazole

Do not stop taking these tablets without first talking to your doctor or pharmacist.

If you have any further questions about the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

The frequency of possible side effects listed below is defined using the following convention:

- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- uncommon (affects 1 to 10 users in 1,000)
- rare (affects 1 to 10 users in 10,000)
- very rare (affects less than 1 user in 10,000)
- not known (frequency cannot be estimated from the available data)

If you get any of the following side effects, stop taking these tablets and tell your doctor immediately, or contact the casualty department at your nearest hospital:

- **Serious allergic reactions (frequency rare):** swelling of the tongue and/or throat, difficulty in swallowing, hives (nettle rash), difficulties in breathing, allergic facial swelling (Quincke's oedema / angioedema), severe dizziness with very fast heartbeat and heavy sweating.
- **Serious skin conditions (frequency not known):** blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme) and sensitivity to light.
- **Other serious conditions (frequency not known):** yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys).

Other side effects are:

- **Uncommon** (affects 1 to 10 users in 1,000) headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; abdominal pain and discomfort; skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders.
 - **Rare** (affects 1 to 10 users in 10,000) disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males.
 - **Very Rare** (affects less than 1 user in 10,000) disorientation.
 - **Not known** (frequency cannot be estimated from the available data) Hallucination, confusion (especially in patients with a history of these symptoms); decreased sodium level in blood.
- If you are on Pantoprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Side effects identified through blood tests:

- **Uncommon** (affects 1 to 10 users in 1,000) an increase in liver enzymes.

- **Rare** (affects 1 to 10 users in 10,000) an increase in bilirubin; increased fats in the blood.
- **Very Rare** (affects less than 1 user in 10,000) a reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; a reduction in the number of white blood cells, which may lead to more frequent infections.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store Pantoprazole 20mg

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

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

Do not store above 30° C.

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

6. Contents of the pack and other information

What Pantoprazole 20 mg contains

The active substance is pantoprazole (as pantoprazole sodium sesquihydrate).

Each gastro-resistant tablet contains 20 mg pantoprazole.

The other ingredients are:

Tablet core: Mannitol 25 (E421), crospovidone (type B), sodium carbonate, anhydrous, hydroxypropyl cellulose (7.5-14.0 cps), calcium stearate.

Seal coating: Hypromellose (3cps), titanium dioxide (E171), ferric oxide yellow (E172), propylene glycol.

Enteric coating: Methylacrylacid-ethylacrylate copolymer (1:1) dispersion 30%, triethyl citrate, talc.

Imprinting ink (Opacode S-1-16530 brown): Shellac glaze, ferric oxide black (E172), ferric oxide red (E172), propylene glycol, ferric oxide yellow (E172), ammonium hydroxide 28%.

What Pantoprazole 20 mg looks like and contents of the pack

Pantoprazole 20 mg are yellow coloured, oval shaped, biconvex, enteric-coated tablets, imprinted with “20” on one side and plain on other side..

Pantoprazole 20mg is available in Alu/Alu blister.

Originals packs of 14, 28 or 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Torrent Pharma (UK) Ltd.
Unit 4, Charlwood Court, County Oak Way,
Crawley, West Sussex, RH11 7XA,
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Telephone: (01293) 574180
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This medicinal product is authorised in the Member States of the EEA under the following names:

The Netherlands: Pantoprazol Heumann 20 mg maagsapresistente tabletten

Italy: Pantoprazolo ABC 20 mg compressa gastro-resistente

Lithuania: Pantoprazole Torrent 20 mg skrandyje neiros tabletės

United Kingdom: Pantoprazole 20 mg gastro-resistant tablets

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REMARK : Folding Length 32 mm					
SUBSTRATE :					
Activities	Department	Name	Signature	Date	
Prepared By	Pkg.Dev				
Reviewed By	Pkg.Dev				
Reviewed By	RA				
Approved By	CQA				



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PACKAGE LEAFLET: INFORMATION FOR THE USER
Pantoprazole 40 mg gastro-resistant tablets
Pantoprazole

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Pantoprazole 40 mg is and what it is used for
2. Before you take Pantoprazole 40 mg
3. How to take Pantoprazole 40 mg
4. Possible side effects
5. How to store Pantoprazole 40 mg
6. Further information

1. WHAT PANTOPRAZOLE 40 MG IS AND WHAT IS IT USED FOR

Pantoprazole is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

Pantoprazole is used for treating:

Adults and adolescents 12 years of age and above:

- Reflux oesophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of stomach acid.

Adults:

- An infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy). The aim is to get rid of the bacteria and so reduce the likelihood of these ulcers returning.
- Stomach and duodenal ulcers.
- Zollinger-Ellison-Syndrome and other conditions producing too much acid in the stomach.

2. BEFORE YOU TAKE PANTOPRAZOLE 40 MG

Do not take Pantoprazole

- If you are allergic (hypersensitive) to pantoprazole or to any of the other ingredients of Pantoprazole (see section 6).
- If you are allergic to medicines containing other proton pump inhibitors.

Take special care with Pantoprazole

- If you have severe liver problems. Please tell your doctor if you ever had problems with your liver in the past. He will check your liver enzymes more frequently, especially when you are taking Pantoprazole as a long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.
 - If you have reduced body stores or risk factors for reduced vitamin B12 and receive pantoprazole long-term treatment. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
 - If you are taking a medicine containing atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- Taking a proton pump inhibitor like Pantoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Tell your doctor immediately if you notice any of the following symptoms:

- an unintentional loss of weight
- repeated vomiting
- difficulty in swallowing
- vomiting blood
- you look pale and feel weak (anaemia)
- you notice blood in your stools

- severe and/or persistent diarrhoea, as Pantoprazole has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

If you take Pantoprazole on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking other medicines

Pantoprazole may influence the effectiveness of other medicines, so tell your doctor if you are taking

- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because Pantoprazole may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Atazanavir (used to treat HIV-infection).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. If you are pregnant, or think you may be pregnant, or if you are breast-feeding, you should use this medicine only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

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

Driving and using machines

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

3. HOW TO TAKE PANTOPRAZOLE 40 MG

Always take Pantoprazole exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

When and how should you take Pantoprazole?

Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

Unless told otherwise by your doctor, the usual dose is:

Adults and adolescents 12 years of age and above:

To treat reflux oesophagitis

The usual dose is one tablet a day. Your doctor may tell you to increase to 2 tablets daily. The treatment period for reflux oesophagitis is usually between 4 and 8 weeks. Your doctor will tell you how long to take your medicine.

Adults:

For the treatment of an infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy).

One tablet, two times a day plus two antibiotic tablets of either amoxicillin, clarithromycin and metronidazole (or tinidazole), each to be taken two times a day with your pantoprazole tablet. Take the first pantoprazole tablet 1 hour before breakfast and the second pantoprazole tablet 1 hour before your evening meal. Follow your doctor's instructions and make sure you read the package leaflets for these antibiotics. The usual treatment period is one to two weeks.

For the treatment of stomach and duodenal ulcers.

The usual dose is one tablet a day. After consultation with your doctor, the dose may be doubled.

Your doctor will tell you how long to take your medicine. The treatment period for stomach ulcers is usually between 4 and 8 weeks. The treatment period for duodenal ulcers is usually between 2 and 4 weeks.

For the long-term treatment of Zollinger-Ellison-Syndrome and of other conditions in which too much stomach acid is produced.

The recommended starting dose is usually two tablets a day. Take the two tablets 1 hour before a meal. Your doctor may later adjust the dose, depending on the amount of stomach acid you produce. If prescribed more than two tablets a day, the tablets should be taken twice daily.

If your doctor prescribes a daily dose of more than four tablets a day, you will be told exactly when to stop taking the medicine.

Special patient groups:

- If you have kidney problems, moderate or severe liver problems, you should not take Pantoprazole for eradication of *Helicobacter pylori*.
- If you suffer from severe liver problems, you should not take more than 20 mg pantoprazole a day (for this purpose tablets containing 20 mg pantoprazole are available on the market).
- Children below 12 years. These tablets are not recommended for use in children below 12 years.

If you take more Pantoprazole than you should

Consult your doctor or pharmacist. There are no known symptoms of overdose.

If you forget to take Pantoprazole

Do not take a double dose to make up for the forgotten dose. Take your next, normal dose at the usual time.

If you stop taking Pantoprazole

Do not stop taking these tablets without first talking to your doctor or pharmacist.

If you have any further questions about the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The frequency of possible side effects listed below is defined using the following convention:

- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- uncommon (affects 1 to 10 users in 1,000)
- rare (affects 1 to 10 users in 10,000)
- very rare (affects less than 1 user in 10,000)
- not known (frequency cannot be estimated from the available data)

If you get any of the following side effects, stop taking these tablets and tell your doctor immediately, or contact the casualty department at your nearest hospital:

- **Serious allergic reactions (frequency rare):** swelling of the tongue and/or throat, difficulty in swallowing, hives (nettle rash), difficulties in breathing, allergic facial swelling (Quincke's oedema / angioedema), severe dizziness with very fast heartbeat and heavy sweating.
- **Serious skin conditions (frequency not known):** blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme) and sensitivity to light.
- **Other serious conditions (frequency not known):** yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys).

Other side effects are:

- **Uncommon** (affects 1 to 10 users in 1,000) headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; abdominal pain and discomfort; skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders.
- **Rare** (affects 1 to 10 users in 10,000) disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males.
- **Very Rare** (affects less than 1 user in 10,000) disorientation.
- **Not known** (frequency cannot be estimated from the available data)

Hallucination, confusion (especially in patients with a history of these symptoms); decreased sodium level in blood.

If you are on Pantoprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Side effects identified through blood tests:

- **Uncommon** (affects 1 to 10 users in 1,000) an increase in liver enzymes.
- **Rare** (affects 1 to 10 users in 10,000) an increase in bilirubin; increased fats in the blood.
- **Very Rare** (affects less than 1 user in 10,000) a reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; a reduction in the number of white blood cells, which may lead to more frequent infections.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PANTOPRAZOLE 40 MG

Keep out of the reach and sight of children.

Do not use Pantoprazole 40 mg after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30° C.

Stability after first opening (for HDPE containers): 100 days

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

The active substance is pantoprazole (as pantoprazole sodium sesquihydrate).

Each gastro-resistant tablet contains 40 mg pantoprazole.

The other ingredients are:

Tablet core: Mannitol 25 (E421), crospovidone (type B), sodium carbonate, anhydrous, hydroxypropylcellulose (7.5-14.0 cps), calcium stearate.

Seal coating: Hypromellose (3 cps), titanium dioxide (E171), ferric oxide yellow (E172), propylene glycol.

Enteric coating: Methacrylicacid-Ethylacrylate copolymer (1:1) dispersion 30%, triethyl citrate, talc.

Imprinting ink (Opacode S-1-16530 brown): Shellac, ferric oxide black (E172), ferric oxide red (E172), propylene glycol, ferric oxide yellow (E172), ammonium hydroxide 28%.

What Pantoprazole 40 mg looks like and contents of the pack

Pantoprazole 40 mg are yellow coloured, oval shaped, biconvex, enteric-coated tablets, imprinted with "40" on one side and plain on other side.

Pantoprazole 40 mg is available in Aluminium-Aluminium blisters containing 14, 15, 28, 30, 49, 50, 56, 60 or 98 gastro-resistant tablets and HDPE bottles with 100 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder And Manufacturer

Torrent Pharma (UK) Ltd.

Unit 4, Charlwood Court,

County Oak Way

Crawley

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REMARK : Folding Length 32 mm					
SUBSTRATE :					
Activities	Department	Name	Signature	Date	
Prepared By	Pkg.Dev				
Reviewed By	Pkg.Dev				
Reviewed By	RA				
Approved By	CQA				



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