DIAFORMIN® VIATRIS

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking DIAFORMIN VIATRIS?

DIAFORMIN VIATRIS contains the active ingredient metformin hydrochloride. DIAFORMIN VIATRIS is used to control blood glucose (the amount of sugar in the blood) in people with diabetes mellitus. For more information, see Section 1. Why am I taking DIAFORMIN VIATRIS? in the full CMI.

2. What should I know before I take DIAFORMIN VIATRIS?

Do not use if you have ever had an allergic reaction to DIAFORMIN VIATRIS or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section 2. What should I know before I take DIAFORMIN VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DIAFORMIN VIATRIS and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take DIAFORMIN VIATRIS?

The dose varies from person to person. The usual starting dose for adults is 500 mg one to two times a day. Your doctor may increase or decrease the dose, depending on your blood glucose levels. More instructions can be found in Section 4. How do I take DIAFORMIN VIATRIS? in the full CMI.

5. What should I know while using DIAFORMIN VIATRIS?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using DIAFORMIN VIATRIS. • Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them. • If you become pregnant while taking DIAFORMIN VIATRIS, tell your doctor immediately. • Check your blood glucose levels regularly.
Things you should not do	• Don't take DIAFORMIN VIATRIS to treat any other complaints unless your doctor tells you to. • Do not skip meals while taking DIAFORMIN VIATRIS. • Do not stop taking your medicine or change the dosage without checking with your doctor.
Driving or using machines	• DIAFORMIN VIATRIS by itself is unlikely to affect how you drive or operate machinery. Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery.
Drinking alcohol	• Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with DIAFORMIN VIATRIS may also lead to serious side effects.
Looking after your medicine	• Keep the pack in a cool, dry place (below 25°C) in its original packaging. • Do not store DIAFORMIN VIATRIS in the bathroom, near a sink, on a window sill or in the car. • Keep your tablets where children cannot reach it.

For more information, see Section 5. What should I know while taking DIAFORMIN VIATRIS? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following and they worry you: nausea, vomiting, diarrhoea, stomach pain, taste disturbance, loss of appetite and skin reactions. Tell your doctor immediately or go to the Emergency Department at the nearest hospital if you notice any of the following symptoms **Tell your doctor immediately or go to the Emergency Department at the nearest hospital if you notice any of the following symptoms**: trouble breathing, feeling weak, tired or generally unwell, unusual muscle pain, sleepiness, dizziness, shivering, feeling extremely cold or slow heart beat. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: Life threatening lactic acidosis (build-up of lactic acid in the blood) can occur due to accumulation of metformin. Risk factors include renal impairment, old age and the use of high doses of metformin above 2 g per day.

DIAFORMIN® VIATRIS

Active ingredient(s): *metformin hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking DIAFORMIN VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DIAFORMIN VIATRIS.**

Where to find information in this leaflet:

1. Why am I taking DIAFORMIN VIATRIS?
2. What should I know before I take DIAFORMIN VIATRIS?
3. What if I am taking other medicines?
4. How do I take DIAFORMIN VIATRIS?
5. What should I know while taking DIAFORMIN VIATRIS?
6. Are there any side effects?
7. Product details

1. Why am I taking DIAFORMIN VIATRIS?

DIAFORMIN VIATRIS contains the active ingredient metformin hydrochloride. DIAFORMIN VIATRIS belongs to a group of medicines called biguanides. DIAFORMIN VIATRIS lowers high blood glucose (hyperglycaemia) by helping your body make better use of the insulin produced by your pancreas.

People with type 2 diabetes are unable to make enough insulin or their body does not respond properly to the insulin it does make. This causes a build up of glucose in the blood, which can lead to serious medical problems.

DIAFORMIN VIATRIS is used to control blood glucose (the amount of sugar in the blood) in people with diabetes mellitus.

DIAFORMIN VIATRIS can be used in type 2 diabetes in adults and children over 10 years of age. It is especially useful in those who are overweight, when diet and exercise are not enough to lower high blood glucose levels (hyperglycaemia).

Long-term hyperglycaemia can lead to heart disease, blindness, kidney damage, poor blood circulation and gangrene. Signs of hyperglycaemia may include:

- tiredness or lack of energy
- headache
- thirst
- passing large amounts of urine
- blurred vision.

For adult patients, metformin can be used alone, or in combination with other oral diabetic medicines or in combination with insulin in insulin requiring type 2 diabetes.

Ask your doctor if you have any questions about why DIAFORMIN VIATRIS has been prescribed for you.

Your doctor may have prescribed DIAFORMIN VIATRIS for another reason.

DIAFORMIN VIATRIS is available only with a doctor's prescription.

There is no evidence that DIAFORMIN VIATRIS is addictive.

2. What should I know before I take DIAFORMIN VIATRIS?

Warnings

Do not use DIAFORMIN VIATRIS if:

- you are allergic to any medicine containing metformin or any other biguanide, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
  - skin rash, itching or hives
  - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
  - wheezing or shortness of breath.

  Always check the ingredients to make sure you can use this medicine.
- you have any of the following conditions:
  - type 1 diabetes mellitus that is well controlled by insulin alone
  - type 2 diabetes that is already well controlled by diet alone
  - any type of metabolic acidosis such as lactic acidosis, diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood - you may notice this as an unusual fruity odour on your breath, difficulty breathing, confusion and frequent urination)
  - severe liver disease
  - excessive alcohol intake, binge drinking, alcohol dependence
  - kidney failure or severe kidney disease
  - dehydration, severe blood loss, shock
  - a severe infection
  - certain heart or blood vessel problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)
  - severe breathing difficulties

- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- gangrene
- inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomiting

- **You need to have major surgery or an examination such as an X-ray or a scan requiring an injection of iodinated contrast (dye).**

  You must stop taking DIAFORMIN VIATRIS for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking DIAFORMIN VIATRIS, ask your doctor.

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives.
- have or have had any other medical conditions:
  - heart or blood vessel problems including heart failure
  - kidney problems
  - liver problem
  - a known or suspected mitochondrial disease e.g. Mitochondrial Encephalopathy with Lactic acidosis, and Stroke-like episodes (MELAS) or Maternal Inherited Diabetes and Deafness (MIDD).
  - hypothyroidism (a condition where the thyroid gland does not produce enough thyroid hormone)

  Your doctor may want to take special care if you have any of these conditions.
- **drink alcohol**

  Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with DIAFORMIN VIATRIS may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

If you have not told your doctor about any of the above, tell him/her before you start taking DIAFORMIN VIATRIS.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or plan to become pregnant.

The safety of DIAFORMIN VIATRIS in pregnant women has not been established.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace DIAFORMIN VIATRIS with insulin while you are pregnant.

Do not take DIAFORMIN VIATRIS if you are breastfeeding.

DIAFORMIN VIATRIS is not recommended while you are breastfeeding. Your doctor will discuss the options available to you.

3. What if I am taking other medicines?

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

Some medicines may interact with DIAFORMIN VIATRIS and affect how it works. These include:

- other medicines used to treat diabetes such as insulin,glitinides, and sulfonylureas
- medicines that contain alcohol, such as cough and cold syrups
- tetracosactide, a medicine used in people with multiple sclerosis, and in young children to treat some types of seizures (fits)
- danazol, a medicine used to treat endometriosis
- some medicines used to treat high blood pressure and some heart conditions, including beta-blockers, calcium channel blockers and ACE inhibitors
- medicines used to prevent blood clots, such as warfarin
- thyroid hormones, such as levothyroxine
- diuretics, also called fluid tablets
- chlorpromazine, a medicine used to treat schizophrenia and other mental illnesses
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to relieve pain, swelling and other symptoms of inflammation, such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen or piroxicam
- cimetidine, a medicine used to treat reflux and ulcers
- corticosteroids such as prednisone or cortisone
- some medicines used to treat asthma such as salbutamol or terbutaline
- medicines that are substrates/ inhibitors of organic cation transporters - OCT 1 such as verapamil; OCT 2 such as dolutegravir, crizotinib, olaparib, daclatasvir or vandetanib
- medicines that are inducers of OCT 1 such as rifampicin
- medicines that may increase the risk of lactic acidosis when concomitantly used with metformin hydrochloride such as topiramate and other carbonic anhydrase inhibitors

These medicines may be affected by DIAFORMIN VIATRIS or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DIAFORMIN VIATRIS.

4. How do I take DIAFORMIN VIATRIS?

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

- The dose varies from person to person. Your doctor will decide the right dose for you.

Adults

- The usual starting dose for adults is 500 mg one to two times a day. Your doctor may increase or decrease the dose, depending on your blood glucose levels. The maximum recommended dose is 1000 mg three times a day.
- The elderly and people with kidney problems may need smaller doses.

Children & Adolescents:

- The usual starting dose for children from 10 years of age and adolescents is one tablet of 500 mg or 850 mg once daily. Your doctor may increase or decrease the dose, depending on your blood glucose levels.
- The maximum recommended dose is 2 g (2000 mg) taken as two or three divided doses.
- If your child has diabetes that is resistant to insulin and is being treated in hospital, your child's doctor will decide the dose.

When to take DIAFORMIN VIATRIS

- **Take DIAFORMIN VIATRIS during or immediately after food.** This will reduce the chance of a stomach upset.
- **Take your medicine at about the same time each day.** Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take DIAFORMIN VIATRIS

- **Swallow the tablets with a glass of water.**
- The 1000 mg tablets can be divided in half along the breakline, if advised by your doctor or pharmacist.

How long to take it for

- **Continue taking your medicine for as long as your doctor tells you to.**
- This medicine helps control diabetes but does not cure it. Most people will need to take DIAFORMIN VIATRIS on a long-term basis.

If you forget to use DIAFORMIN VIATRIS

DIAFORMIN VIATRIS should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember (with food), and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too many DIAFORMIN VIATRIS

If you think that you or anyone else have taken too many DIAFORMIN VIATRIS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**Australia telephone 13 11 26**) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too many DIAFORMIN VIATRIS, you may feel sleepy, very tired, sick, vomit, have trouble breathing and have unusual muscle pain, stomach pain or diarrhoea. These may be early signs of a serious condition called lactic acidosis (build up of lactic acid in the blood).

You may also experience symptoms of hypoglycaemia (low blood glucose). This usually only happens if you take too many DIAFORMIN VIATRIS together with other medicines for diabetes or with alcohol.

If you do experience any signs of hypoglycaemia, raise your blood glucose quickly by eating jelly beans, sugar or honey, drinking a non-diet soft drink or taking glucose tablets.

5. What should I know while taking DIAFORMIN VIATRIS?

Things you must do

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia (low blood sugar) and hyperglycaemia (high blood sugar) and know how to treat them.

HYPOGLYCAEMIA

DIAFORMIN VIATRIS does not normally cause hypoglycaemia (low blood sugar), although you may experience it if you take other medicines for diabetes such as sulfonylureas or repaglinide; or if you also use insulin.

Hypoglycaemia can occur suddenly. Initial signs may include:

- weakness, trembling or shaking

- sweating
- lightheadedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2 to 3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

HYPERGLYCAEMIA

If you notice the return of any of the signs of hyperglycaemia (high blood sugar), contact your doctor immediately.

Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less DIAFORMIN VIATRIS than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- are having surgery (including dental surgery)

Your blood glucose may become difficult to control at these times. You may also be more at risk of developing a serious condition called lactic acidosis. At these times, your doctor may replace DIAFORMIN VIATRIS with insulin.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DIAFORMIN VIATRIS.

Tell all the other doctors, dentists and pharmacists who treat you that you are taking DIAFORMIN VIATRIS.

If you become pregnant while taking DIAFORMIN VIATRIS, tell your doctor immediately.

Tell your doctor if any of the following happen:

- you become ill
- you become dehydrated (for instance due to persistent or severe diarrhoea or recurrent vomiting)
- you are injured
- you have a fever
- you have a serious infection such an influenza, respiratory tract infection or urinary tract infection
- you are having major surgery
- you are having an examination such as an X-ray or a scan requiring an injection of an iodinated contrast agent (dye)
- you become pregnant.

Your blood glucose may become difficult to control at these times. You may also be more at risk of developing a serious condition called lactic acidosis. At these times, your doctor may replace DIAFORMIN VIATRIS with insulin

Visit your doctor regularly for check ups.

Your doctor may want to perform blood tests to check your kidneys, liver, heart and vitamin B12 level while you are taking DIAFORMIN VIATRIS.

Check your blood glucose levels regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

When you start treatment with DIAFORMIN VIATRIS, it can take up to two weeks for your blood glucose levels to be properly controlled.

Carefully follow the advice of your doctor and dietician on diet, drinking alcohol and exercise.

Things you should not do

- **Do not take DIAFORMIN VIATRIS to treat any other complaints unless your doctor tells you to.**
- **Do not give your medicine to anyone else, even if they have the same condition as you.**
- **Do not skip meals while taking DIAFORMIN VIATRIS.**
- **Do not stop taking your medicine or change the dosage without checking with your doctor.**

Things to be careful of

If you become sick with a cold, fever or flu, it is very important to continue eating your normal meals.

Your diabetes educator or dietician can give you a list of foods to eat on sick days.

When you are travelling, it is a good idea to:

- wear some form of identification (e.g. bracelet) showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, for example, sugar sachets or jelly beans
- carry emergency food rations in case of a delay, for example, dried fruit, biscuits or muesli bars
- bring enough DIAFORMIN VIATRIS with you, so you don't miss any doses

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid second-hand smoke
- Limit alcohol intake
- Enjoy healthy eating by:
    - eating plenty of vegetables and fruit;
    - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products)
- Be active. Progress, over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active
- Maintain a healthy weight
- Discuss your lifestyle and lifestyle plans with your doctor
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost)

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit)

If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Driving or using machines

If you have to be alert, for example when driving, be especially careful not to let your blood glucose levels fall too low.

Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse. However, DIAFORMIN VIATRIS by itself is unlikely to affect how you drive or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with DIAFORMIN VIATRIS may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

Looking after your medicine

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store DIAFORMIN VIATRIS or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to dispose of your medicine

- **If your doctor tells you to stop taking DIAFORMIN VIATRIS**
- After the expiry date.

Getting rid of any unwanted medicine

6. Take it to any pharmacy for safe disposal. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DIAFORMIN VIATRIS.

DIAFORMIN VIATRIS helps most people with diabetes but it may have unwanted side effects in some people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• feeling sick (nausea) • vomiting • diarrhoea • stomach pain • taste disturbance • loss of appetite • skin reactions such as redness of the skin, itching or an itchy rash (urticaria).	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

These are generally mild side effects which disappear after the first few weeks. Taking DIAFORMIN VIATRIS with meals can help reduce stomach pain, nausea and diarrhoea. Skin reactions have been reported rarely.

Serious side effects

Serious side effects	What to do
• nausea, vomiting, stomach pain • trouble breathing • feeling weak, tired or generally unwell • unusual muscle pain • sleepiness • dizziness or lightheadedness • shivering, feeling extremely cold • slow heartbeat	**Tell your doctor immediately or go to the Emergency Department at the nearest hospital if you notice any of the following symptoms of lactic acidosis (build up of lactic acid in the blood).**

Lactic acidosis is a very rare but serious side effect requiring urgent medical attention or hospitalisation. Although rare, if lactic acidosis does occur, it can be fatal. The risk of lactic acidosis is higher in the elderly, those whose diabetes is poorly controlled, those with prolonged fasting, those with certain heart conditions, those who drink alcohol and those with kidney or liver problems and those with mitochondrial diseases.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some side effects (e.g. reduced vitamin B12 level) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What DIAFORMIN VIATRIS contains

Active ingredient (metformin hydrochloride)	The active ingredient in DIAFORMIN VIATRIS is metformin hydrochloride. It is available in three strengths: • 500 mg of metformin hydrochloride. • 850 mg of metformin hydrochloride. • 1000 mg of metformin hydrochloride.
Other ingredients (inactive ingredients)	• povidone • magnesium stearate • OPADRY complete film coating system 20C59060 Clear (ID 106044)

Do not take this medicine if you are allergic to any of these ingredients.

What DIAFORMIN VIATRIS looks like

DIAFORMIN VIATRIS 1000 mg is a white, oval, film coated tablet, debossed “MF” and “3” on either side of the break line on one side and “G” on the other side (AUST R 206735).

Each blister pack contains 90 tablets.

Who distributes DIAFORMIN VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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DIAFORMIN® is a Viatris company trade mark

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