Package leaflet: Information for the user

RISPERDAL® 1 mg/ml oral solution

risperidone

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Risperdal is and what it is used for

Risperdal belongs to a group of medicines called 'antipsychotics'.
Risperdal is used to treat the following:
- Schizophrenia, where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious, or confused
- Mania, where you may feel very excited, elated, agitated, enthusiastic or hyperactive. Mania occurs in an illness called "bipolar disorder"
- Short-term treatment (up to 6 weeks) of long-term aggression in people with Alzheimer's dementia, who harm themselves or others. Alternative (non-drug) treatments should have been used previously
- Short-term treatment (up to 6 weeks) of long-term aggression in intellectually disabled children (at least 5 years of age) and adolescents with conduct disorder.

Risperdal can help alleviate the symptoms of your disease and stop your symptoms from coming back.

2. What you need to know before you take Risperdal

Do not take Risperdal
- If you are allergic to risperidone or any of the other ingredients of this medicine (listed in section 6).

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Risperdal.

Warnings and precautions
Talk to your doctor or pharmacist before taking Risperdal if:
- You have a heart problem. Examples include an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure. Risperdal may cause low blood pressure. Your dose may need to be adjusted
- You know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain
- You have ever experienced involuntary movements of the tongue, mouth and face
- You have ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome)
- You have Parkinson's disease or dementia
- You know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines)
- You are diabetic
- You have epilepsy
- You are a man and you have ever had a prolonged or painful erection
- You have problems controlling your body temperature or overheating
- You have kidney problems
- You have liver problems
- You have an abnormally high level of the hormone prolactin in your blood or if you have a possible prolactin-dependent tumour.
- You or someone else in your family has a history of blood clots, as antipsychotics have been associated with formation of blood clots.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Risperdal.
As dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood has been seen very rarely with patients taking Risperdal, your doctor may check your white blood cell counts.
Risperdal may cause you to gain weight. Significant weight gain may adversely affect your health. Your doctor should regularly measure your body weight.
As diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking Risperdal, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly.
Risperdal commonly raises levels of a hormone called "prolactin". This may cause side effects such as menstrual disorders or fertility problems in women, breast swelling in men (see Possible side effects). If such side effects occur, evaluation of the prolactin level in the blood is recommended.
During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the coloured part of the eye) may become floppy during surgery and that may lead to eye damage. If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are taking this medicine.

Elderly people with dementia
In elderly patients with dementia, there is an increased risk of stroke. You should not take risperidone if you have dementia caused by stroke. During treatment with risperidone you should frequently see your doctor. Medical treatment should be sought straight away if you or your caregiver notice a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke.

Children and adolescents
Before treatment is started for conduct disorder, other causes of aggressive behaviour should have been ruled out.
If during treatment with risperidone tiredness occurs, a change in the time of administration might improve attention difficulties.
Before treatment is started your, or your child's body weight may be measured and it may be regularly monitored during treatment.
A small and inconclusive study has reported an increase in height in children who took risperidone, but whether this is an effect of the drug or due to some other reason is not known.

Other medicines and Risperdal
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to talk to your doctor or pharmacist if you are taking any of the following
- Medicines that work on your brain such as to help you calm down (benzodiazepines) or some medicines for pain (opiates), medicines for allergy (some antihistamines), as risperidone may increase the sedative effect of all of these
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems, allergies (antihistamines), some antidepressants or other medicines for mental problems
- Medicines that cause a slow heart beat
- Medicines that cause low blood potassium (such as certain diuretics)
- Medicines to treat raised blood pressure. Risperdal can lower blood pressure
- Medicines for Parkinson's disease (such as levodopa)
- Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate)
- Water tablets (diuretics) used for heart problems or swelling of parts of your body due to a build up of too much fluid (such as furosemide or chlorothiazide). Risperdal taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia.

The following medicines may reduce the effect of risperidone
- Rifampicin (a medicine for treating some infections)
- Carbamazepine, phenytoin (medicines for epilepsy)
- Phenobarbital.

If you start or stop taking such medicines you may need a different dose of risperidone.

The following medicines may increase the effect of risperidone
- Quinidine (used for certain types of heart disease)
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants
- Medicines known as beta-blockers (used to treat high blood pressure)
- Phenothiazines (such as medicines used to treat psychosis or to calm down)
- Cimetidine, ranitidine (blockers of the acidity of stomach)
- Itraconazole and ketoconazole (medicines for treating fungal infections)
- Certain medicines used in the treatment of HIV/AIDS, such as ritonavir
- Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders.

If you start or stop taking such medicines you may need a different dose of risperidone.
If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Risperdal.

Risperdal with food, drink and alcohol
You can take this medicine with or without food. You should avoid drinking alcohol when taking Risperdal.

Pregnancy, breast-feeding and fertility
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide if you can take it
- The following symptoms may occur in newborn babies, of mothers that have used Risperdal in the last trimester (last three months of their pregnancy): shaking, muscle stiffness, and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor
- Risperdal can raise your levels of a hormone called "prolactin" that may impact fertility (see Possible side effects).

Driving and using machines
Dizziness, tiredness, and vision problems may occur during treatment with Risperdal. Do not drive or use any tools or machines without talking to your doctor first.

Risperdal oral solution contains benzoic acid (E 210) and sodium
This medicine contains 2 mg benzoic acid in each 1 ml of oral solution. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say, essentially 'sodium free'.

3. How to take Risperdal

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose is as follows:
For the treatment of schizophrenia
Adults
- The usual starting dose is 2 mg per day, this may be increased to 4 mg per day on the second day
- Your dose may then be adjusted by your doctor depending on how you respond to the treatment
- Most people feel better with daily doses of 4 to 6 mg
- This total daily dose can be divided into either one or two doses a day. Your doctor will tell you which is the best for you.

Elderly people
- Your starting dose will normally be 0.5 mg twice a day
- Your dose may then be gradually increased by your doctor to 1 mg to 2 mg twice a day
- Your doctor will tell you which is the best for you.

For the treatment of mania
Adults
- Your starting dose will usually be 2 mg once a day
- Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment
- Most people feel better with doses of 1 to 6 mg once a day.

Elderly people
- Your starting dose will usually be 0.5 mg twice a day
- Your dose may then be gradually adjusted by your doctor to 1 mg to 2 mg twice a day depending on how much you respond to the treatment.

For the treatment of long-standing aggression in people with Alzheimer's dementia
Adults (including elderly people)
- Your starting dose will normally be 0.25 mg (0.25 ml of Risperdal oral solution 1 mg/ml) twice a day
- Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment
- Most people feel better with 0.5 mg twice a day. Some patients may need 1 mg twice a day
- Treatment duration in patients with Alzheimer's dementia should be not more than 6 weeks.

Use in children and adolescents
- Children and adolescents under 18 years old should not be treated with Risperdal for schizophrenia or mania.

For the treatment of conduct disorder
The dose will depend on your child's weight:
For children who weigh less than 50 kg
- The starting dose will normally be 0.25 mg (0.25 ml of Risperdal oral solution 1 mg/ml) once a day
- The dose may be increased every other day in steps of 0.25 mg per day
- The usual maintenance dose is 0.25 mg to 0.75 mg (0.25 ml to 0.75 ml of Risperdal oral solution 1 mg/ml) once a day.

For children who weigh 50 kg or more
- The starting dose will normally be 0.5 mg once a day
- The dose may be increased every other day in steps of 0.5 mg per day
- The usual maintenance dose is 0.5 mg to 1.5 mg once a day.

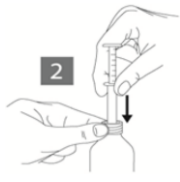
Treatment duration in patients with conduct disorder should be not more than 6 weeks.
Children under 5 years old should not be treated with Risperdal for conduct disorder.

People with kidney or liver problems
Regardless of the disease to be treated, all starting doses and following doses of risperidone should be halved. Dose increases should be slower in these patients. Risperidone should be used with caution in this patient group.

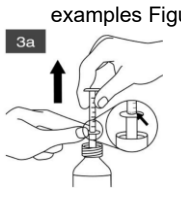
Method of administration
FOR ORAL USE
The solution comes with a syringe (pipette). Use only the syringe (pipette) delivered with this medicine for measuring the dose prescribed by the physician.
Follow these steps:
1. Remove the child-proof cap. Push the plastic screw cap down while turning it counter clockwise (Figure 1)



2. Insert the syringe into the bottle (Figure 2)

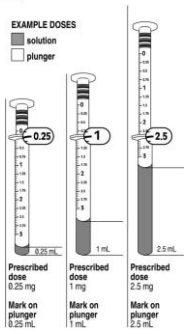


3. While holding the bottom ring (Figure 3a), pull the top ring up to the mark that corresponds to the number of millilitres or mg you need to take Always read the mark aligning to the bottom ring (See examples Figure 3b)

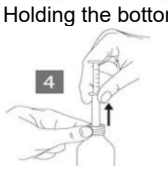


Measure the exact dose of medicine you need. Pay attention when measuring a small dose, for example for 0.25 mg measure 0.25 ml (a quarter millilitre); for 0.5 mg measure 0.5 ml (half a millilitre). 1 ml of Risperdal oral solution contains 1 mg risperidone. The measured volume is printed every 0.25 ml / 0.25 mg on the plunger.
Figure 3b shows **examples** of prescribed doses and corresponding marks on the plunger.

3b



4. Holding the bottom ring, remove the entire syringe from the bottle (Figure 4)



5. Empty the syringe into any non-alcoholic drink, except for tea. Slide the upper ring down
6. Close the bottle
7. Rinse the syringe with some water and let it air dry.

If you take more Risperdal than you should
- See a doctor right away. Take the medicine pack with you
- In case of overdose you may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heartbeats or fits.

If you forget to take Risperdal
- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor
- **Do not take a double dose (two doses at the same time) to make up for a forgotten dose.**

If you stop taking Risperdal
You should not stop taking this medicine unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop this medicine, your dose may be decreased gradually over a few days.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Tell your doctor immediately if you experience any of the following uncommon side effects (may affect up to 1 in 100 people):
- Have dementia and experience a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke
- Experience tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body). Tell your doctor immediately if you experience involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of Risperdal may be needed

Tell your doctor immediately if you experience any of the following rare side effects (may affect up to 1 in 1,000 people):
- Experience blood clots in the veins, especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty breathing. If you notice any of these symptoms seek medical advice immediately
- Experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”). Immediate medical treatment may be needed
- Are a man and experience prolonged or painful erection. This is called priapism. Immediate medical treatment may be needed
- Experience severe allergic reaction characterised by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash or drop in blood pressure.

The following other side effects may also happen:
Very common side effects (may affect more than 1 in 10 people):
- Difficulty falling or staying asleep
- Parkinsonism: This condition may include: slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement "freezing up" and then restarting. Other signs of parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face
- Feeling sleepy, or less alert
- Headache.

Common side effects (may affect up to 1 in 10 people):
- Pneumonia, infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, ear infection, feeling like you have the flu
- Raised levels of a hormone called "prolactin" found in a blood test (which may or may not cause symptoms). Symptoms of high prolactin occur uncommonly and may include in men breast swelling, difficulty in getting or maintaining erections, decreased sexual desire or other sexual dysfunction. In women they may include breast discomfort, leakage of milk from the breasts, missed menstrual periods, or other problems with your cycle or fertility problems
- Weight gain, increased appetite, decreased appetite
- Sleep disorder, irritability, depression, anxiety, restlessness
- Dystonia: This is a condition involving slow or sustained involuntary contraction of muscles. While it can involve any part of the body (and may result in abnormal posture), dystonia often involves muscles of the face, including abnormal movements of the eyes, mouth, tongue or jaw
- Dizziness
- Dyskinesia: This is a condition involving involuntary muscle movements, and can include repetitive, spastic or writhing movements, or twitching
- Tremor (shaking)
- Blurry vision, eye infection or "pink eye"
- Rapid heart rate, high blood pressure, shortness of breath
- Sore throat, cough, nosebleeds, stuffy nose
- Abdominal pain, abdominal discomfort, vomiting, nausea, constipation, diarrhea, indigestion, dry mouth, toothache
- Rash, skin redness
- Muscle spasms, bone or muscle ache, back pain, joint pain
- Incontinence (lack of control) of urine
- Swelling of the body, arms or legs, fever, chest pain, weakness, fatigue (tiredness), pain
- Fall.

Uncommon side effects (may affect up to 1 in 100 people):
- Infection of the breathing passages, bladder infection, eye infection, tonsillitis, fungal infection of the nails, infection of the skin, an infection confined to a single area of skin or part of the body, viral infection, skin inflammation caused by mites
- Decrease in the type of white blood cells that help to protect you against infection, white blood cell count decreased, decrease in platelets (blood cells that help you stop bleeding), anaemia, decrease in red blood cells, increase in eosinophils (a type of white blood cell) in your blood
- Allergic reaction
- Diabetes or worsening of diabetes, high blood sugar, excessive drinking of water
- Weight loss, loss of appetite resulting in malnutrition and low body weight
- Increased cholesterol in your blood
- Elated mood (mania), confusion, decreased sexual drive, nervousness, nightmares
- Unresponsive to stimuli, loss of consciousness, low level of consciousness
- Convulsion (fits), fainting
- A restless urge to move parts of your body, balance disorder, abnormal coordination, dizziness upon standing, disturbance in attention, problems with speech, loss or abnormal sense of taste, reduced sensation of skin to pain and touch, a sensation of tingling, pricking, or numbness skin
- Oversensitivity of the eyes to light, dry eye, increased tears, redness of the eyes
- Sensation of spinning (vertigo), ringing in the ears, ear pain
- Atrial fibrillation (an abnormal heart rhythm), an interruption in conduction between the upper and lower parts of the heart, abnormal electrical conduction of the heart, prolongation of the QT interval from your heart, slow heart rate, abnormal electrical tracing of the heart (electrocardiogram or ECG), a fluttering or pounding feeling in your chest (palpitations)
- Low blood pressure, low blood pressure upon standing (consequently, some people taking Risperdal may feel faint, dizzy, or may pass out when they stand up or sit up suddenly, flushing
- Pneumonia caused by inhaling food, lung congestion, congestion of breathing passages, crackly lung sounds, wheezing, voice disorder, breathing passage disorder
- Stomach or intestinal infection, stool incontinence, very hard stool, difficulty swallowing, excessive passing of gas or wind
- Hives (or "nettle rash"), itching, hair loss, thickening of skin, eczema, dry skin, skin discolouration, acne, flaky, itchy scalp or skin, skin disorder, skin lesion
- An increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown
- Abnormal posture, joint stiffness, joint swelling, muscle weakness, neck pain
- Frequent passing of urine, inability to pass urine, pain when passing urine
- Erectile dysfunction, ejaculation disorder
- Loss of menstrual periods, missed menstrual periods or other problems with your cycle (females)
- Development of breasts in men, leakage of milk from the breasts, sexual dysfunction, breast pain, breast discomfort, vaginal discharge
- Swelling of the face, mouth, eyes, or lips
- Chills, an increase in body temperature
- A change in the way you walk
- Feeling thirsty, feeling unwell, chest discomfort, feeling "out of sorts", discomfort
- Increased liver transaminases in your blood, increased GGT (a liver enzyme called gamma-glutamyltransferase) in your blood, increased liver enzymes in your blood
- Procedural pain.

Rare side effects (may affect up to 1 in 1,000 people):
- Infection
- Inappropriate secretion of a hormone that controls urine volume
- Sleep walking
- Sleep-related eating disorder
- Sugar in the urine, low blood sugar, high blood triglycerides (a fat)
- Lack of emotion, inability to reach orgasm
- Not moving or responding while awake (catatonia)
- Blood vessel problems in the brain
- Coma due to uncontrolled diabetes
- Shaking of the head
- Glaucoma (increased pressure within the eyeball), problems with movement of your eyes, eye rolling, eyelid margin crusting
- Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken Risperdal. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken this medicine
- Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood
- Dangerously excessive intake of water
- Irregular heart beat
- Trouble breathing during sleep (sleep apnea), fast, shallow breathing
- Inflammation of the pancreas, a blockage in the bowels
- Swollen tongue, chapped lips, rash on skin related to drug
- Dandruff
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis)
- A delay in menstrual periods, enlargement of the glands in your breasts, breast enlargement, discharge from the breasts
- Increased insulin (a hormone that controls blood sugar levels) in your blood
- Hardening of the skin
- Decreased body temperature, coldness in arms and legs
- Symptoms of drug withdrawal
- Yellowing of the skin and the eyes (jaundice).

Very rare side effects (may affect up to 1 in 10,000 people):
- Life threatening complications of uncontrolled diabetes
- Serious allergic reaction with swelling that may involve the throat and lead to difficulty breathing
- Lack of bowel muscle movement that causes blockage.

Not known: frequency cannot be estimated from the available data
- Severe or life-threatening rash with blisters and peeling skin that may start in and around the mouth, nose, eyes, and genitals and spread to other areas of the body (Stevens-Johnson syndrome or toxic epidermal necrolysis).

The following side effect has been seen with the use of another medicine called paliperidone that is very similar to risperidone, so these can also be expected with Risperdal: Rapid heartbeat upon standing.

Additional side effects in children and adolescents
In general, side effects in children are expected to be similar to those in adults. The following side effects were reported more often in children and adolescents (5 to 17 years)
than in adults: feeling sleepy, or less alert, fatigue (tiredness), headache, increased appetite, vomiting, common cold symptoms, nasal congestion, abdominal pain, dizziness, cough, fever, tremor (shaking), diarrhoea, and incontinence (lack of control) of urine.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Risperdal

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 and bottle. The expiry date refers to the last day of that month.
Do not store above 30°C. Do not refrigerate or freeze.
Once the bottle is opened, any unused portion of Risperdal oral solution should be discarded after 3 months.
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 Risperdal contains
The active substance is risperidone
1 ml Risperdal oral solution contains 1 mg risperidone.
The other ingredients are:
Tartaric acid, Benzoic acid, Sodium hydroxide, Purified water
What Risperdal looks like and contents of the pack
Risperdal oral solution is supplied in an amber bottle with a child-resistant cap containing 100 ml of a clear, colourless liquid. A dosing pipette is also provided.
The pipette supplied with the bottle size of 100 ml is graduated in milligrams and millilitres with a minimum volume of 0.25 ml and a maximum volume of 3 ml. Graduation marks in 0.25 ml (equals 0.25 mg oral solution) increments up to 3 ml (equals 3 mg oral solution) are printed on this pipette.
Manufacturer: Janssen Pharmaceutica NV, Turnhoutseweg 30, 2340 Beerse, Belgium.
Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.
Parallel Product Authorisation Number: PPA0465/525/001
Risperdal is a registered trademark of Janssen-Cilag Ltd.
This medicine is authorised in the Member States of the European Economic Area under the following names:
Austria: Risperdal
Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden: RISPERDAL
Germany: Risperdal Lösung 1 mg/ml
Latvia, Poland, Estonia, Lithuania, Romania: RISPOLEPT
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