

OLMERTAN COMBI TABLETS

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 using OLMERTAN COMBI TABLETS ?

OLMERTAN COMBI TABLETS contains the active ingredient Olmesartan medoxomil and hydrochlorothiazide. Olmesartan medoxomil and hydrochlorothiazide is used to treat high blood pressure (hypertension). For more information, see Section [1. Why am I using OLMERTAN COMBI TABLETS ?](#) in the full CMI.

2. What should I know before I use OLMERTAN COMBI TABLETS ?

Do not use if you have ever had an allergic reaction to OLMERTAN COMBI TABLETS 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 use OLMERTAN COMBI TABLETS ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OLMERTAN COMBI TABLETS 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 use OLMERTAN COMBI TABLETS ?

The dose of OLMERTAN COMBI TABLETS is one tablet to be taken once a day or talk to your doctor before taking this medicine. Follow all directions given to you by your doctor and pharmacist carefully. More instructions can be found in Section [4. How do I use OLMERTAN COMBI TABLETS ?](#) in the full CMI.

5. What should I know while using OLMERTAN COMBI TABLETS ?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using OLMERTAN COMBI TABLETS .• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking OLMERTAN COMBI TABLETS .• If you need to have any blood tests, tell your doctor you are taking OLMERTAN COMBI TABLETS may affect the results of some laboratory tests.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their condition seems similar to yours.• Do not use it to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• OLMERTAN COMBI TABLETS may cause dizziness, light-headedness or tiredness in some people.• There have been side effects reported with OLMERTAN COMBI TABLETS that may affect your ability to drive or operate machinery. Individual responses to OLMERTAN COMBI TABLETS may vary. Be careful before you drive or use any machines or tools until you know how OLMERTAN COMBI TABLETS affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol while using the medicine

Looking after your medicine	<ul style="list-style-type: none">• Store OLMERTAN COMBI TABLETS below 25°C in a cool dry place.• Do not store OLMERTAN COMBI TABLETS or any other medicine in the bathroom or near a sink. Do not leave it in the car or on windowsills. Do not leave it on a windowsill or in the car on hot days.• Keep OLMERTAN COMBI TABLETS and all other medicines where children cannot reach them.
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For more information, see Section [5. What should I know while using OLMERTAN COMBI TABLETS](#) in the full CMI.

6. Are there any side effects?

Tell your doctor if you experience any of the following: feeling light-headed, dizzy or faint, cough, headache, feeling sick (nausea) or vomiting, stomach pain, diarrhoea or constipation, an uncomfortable feeling in the stomach, unusual tiredness or weakness, fatigue, 'flu-like' symptoms, runny or blocked nose, or sneezing, bronchitis, sore throat and discomfort when swallowing (pharyngitis), swelling of the hands, feet or ankles, back pain, urinary tract infection, jaundice, blurred vision, skin rashes or eczema, sleep disturbance, depression.

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.](#)

OLMERTAN COMBI TABLETS

Olmesartan medoxomil and hydrochlorothiazide

Consumer Medicine Information (CMI)

This leaflet provides important information about using OLMERTAN COMBI TABLETS. **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 OLMERTAN COMBI TABLETS.**

Where to find information in this leaflet:

- [1. Why am I using OLMERTAN COMBI TABLETS ?](#)
- [2. What should I know before I use OLMERTAN COMBI TABLETS ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use OLMERTAN COMBI TABLETS ?](#)
- [5. What should I know while using OLMERTAN COMBI TABLETS ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using OLMERTAN COMBI TABLETS ?

OLMERTAN COMBI TABLETS contains the active ingredient Olmesartan medoxomil and hydrochlorothiazide.

OLMERTAN COMBI TABLETS is used to treat high blood pressure which is sometimes called hypertension.

Everyone has blood pressure. This pressure helps push blood all around your body. Your blood pressure changes at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems including stroke, heart disease and kidney failure.

How OLMERTAN COMBI TABLETS works

OLMERTAN COMBI TABLETS belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance

produced in the body which causes blood vessels to tighten. OLMERTAN COMBI TABLETS blocks the action of angiotensin-II and therefore relaxes your blood vessels. This helps lower your blood pressure.

OLMERTAN COMBI TABLETS also contains a diuretic which reduces the amount of fluid in the body. This also helps to lower blood pressure.

Your doctor may have prescribed OLMERTAN COMBI TABLETS for another reason. Ask your doctor if you have any questions about why OLMERTAN COMBI TABLETS has been prescribed for you.

OLMERTAN COMBI TABLETS is not addictive.

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

2. What should I know before I use OLMERTAN COMBI TABLETS ?

Warnings

Do not use OLMERTAN COMBI TABLETS if you are allergy to:

- Olmesartan medoxomil and hydrochlorothiazide or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- olmesartan, sulfonamide derived medicines (e.g. thiazide diuretics).

Symptoms of an allergic reaction may include skin rash, itching, hives, shortness of breath, difficulty breathing, swelling of the face, lips, tongue, muscle pain or tenderness or joint pain.

Check with your doctor if:

- you have serious problems with your kidneys
- you have serious problems with your liver
- you have low potassium or sodium levels in the blood
- you have high calcium or uric acid levels in the blood.
- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.

Do not take OLMERTAN COMBI TABLETS if you are pregnant or breastfeeding.

OLMERTAN COMBI TABLETS may enter your womb or it may pass into the breast milk and there is the possibility that your baby may be affected.

If pregnancy is discovered OLMERTAN COMBI TABLETS should be discontinued as soon as possible.

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

If you are not sure whether you should start taking OLMERTAN COMBI TABLETS, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems
- liver problems
- heart problems
- diabetes
- excessive vomiting or diarrhoea recently
- gout
- Systemic Lupus Erythematosus (SLE)
- high levels of potassium in your blood.
- problems with your adrenal glands (small glands above the kidneys)

You must also tell your doctor if you:

- are following a very low salt diet
- you are or intend to become pregnant or plan to breastfeed.
- you are taking potassium supplements, potassium-sparing agents, potassium-containing salt substitutes or other medicines that may increase serum potassium (e.g., trimethoprim-containing products).
- you have skin cancer or if you develop a new skin lesion during treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Discuss with

your doctor how to protect your skin from sun exposure, and avoid artificial tanning.

If you have not told your doctor about any of the above, tell him/ her before you start taking OLMERTAN COMBI TABLETS

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Taking other medicines

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

Some medicines may interfere with OLMERTAN COMBI TABLETS and affects how it works.

These include:

- other medicines used to treat high blood pressure
- other diuretics, also known as fluid or water TABLETS
- non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- potassium supplements or potassium-containing salt substitutes
- other medicines that may increase serum potassium (e.g., trimethoprim-containing products)
- lithium or antidepressant medicines
- insulin and TABLETS used to treat diabetes
- antacids, medicines used to treat heartburn and indigestion
- medicines which lower your immune system, such as corticosteroids and cytotoxic medicines used to treat cancer (including radiation therapy)

- alcohol
- laxatives, medicines used to treat constipation
- medicines used to relieve pain
- medicines used to treat epilepsy
- antiarrhythmics which treat irregular heart beats
- muscle relaxants
- cholestyramine and colestipol, used to treat high cholesterol
- any medicine that contains aliskiren
- any medicines that contain colesevelam.

These medicines may be affected by OLMERTAN COMBI TABLETS or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines.

Other medicines not listed above may also interfere with OLMERTAN COMBI TABLETS . Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Use in children

The safety and effectiveness of OLMERTAN COMBI TABLETS in children has not been established.

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

4. How do I use OLMERTAN COMBI TABLETS?

How much to take / use

- Follow the instructions provided and use OLMERTAN COMBI TABLETS until your doctor tells you to stop.
- Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you which OLMERTAN COMBI TABLETS you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

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

How much to take

The dose of OLMERTAN COMBI TABLETS is one tablets to be taken once a day.

How to take it

Swallow the TABLETS whole with full glass of water. Do not crush, chew, break or dissolve the tablets.

When to take it

Take your medicine at about the same time each day with or without food.

Taking your TABLETS at the same time each day will have the best effect.

It will also help you remember when to take the TABLETS. It does not matter whether you take it with or without food.

How long to take it

OLMERTAN COMBI TABLETS helps control your condition, but does not cure it. Therefore, you must take OLMERTAN COMBI TABLETS every day. Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

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 it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

remembering to take your medicine, ask your pharmacist for some hints.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

If you take too much (overdose)

If you think that you have used too much OLMERTAN COMBI TABLETS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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

Keep telephone numbers for these places handy.

If you take too much OLMERTAN COMBI TABLETS, you may feel light-headed, dizzy or you may faint. You may also have a fast heartbeat.

5. What should I know while using OLMERTAN COMBI TABLETS ?

Things you should do

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

Make sure you drink enough water during exercise and hot weather when you are taking OLMERTAN COMBI TABLETS, especially if you sweat a lot.

If you do not drink enough water while taking OLMERTAN COMBI TABLETS, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

If you have excess vomiting and/or diarrhoea, while taking OLMERTAN COMBI TABLETS, tell your doctor.

You may lose too much water and salt and your blood pressure may drop too much.

If you feel light-headed or dizzy after taking your first dose of OLMERTAN COMBI TABLETS, or when your dose is increased, tell your doctor immediately.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking OLMERTAN COMBI TABLETS.

Your blood pressure may drop suddenly.

If you become pregnant while taking OLMERTAN COMBI TABLETS, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking OLMERTAN COMBI TABLETS.

OLMERTAN COMBI TABLETS may interfere with the results of some tests.

Tell your doctor if photosensitivity reaction occurs during your treatment.

Tell your doctor immediately in case of acute onset of decreased visual acuity or ocular pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking OLMERTAN COMBI TABLETS. This can lead to permanent vision loss, if not treated.

Tell your doctor immediately if you experience any fever, severe shortness of breath, breathing faster than normal, difficulty breathing, slightly blue fingertips and lips after taking OLMERTAN COMBI TABLETS. Stop the medication and seek medical attention immediately.

Have your blood pressure checked when your doctor says, to make sure OLMERTAN COMBI TABLETS is working.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.

Things you should not do

- **Do not give OLMERTAN COMBI TABLETS to anyone else, even if they have the same condition as you.**
- **Do not take OLMERTAN COMBI TABLETS to treat any other complaints unless your doctor or pharmacist tells you to.**
- **Do not stop taking OLMERTAN COMBI TABLETS, or lower the dosage, without checking with your doctor.**

Things to be careful of

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how OLMERTAN COMBI TABLETS affects you.

As with other medicines in this class, OLMERTAN COMBI TABLETS may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to OLMERTAN COMBI TABLETS before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or lightheadedness may be worse.

Drinking alcohol

Tell your doctor your doctor if you drink alcohol. They may advise you to limit your alcohol intake

Things that would be helpful for your blood pressure

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol** - your doctor may advise you to limit your alcohol intake.
- **Weight**: your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.
- **Diet**: eat a healthy diet which includes plenty of fresh vegetables, fruit, bread (preferably wholegrain), cereals and fish. Also eat less sugar and fat (especially saturated fat) which includes sausages, fatty meats, full cream dairy products, biscuits, cakes, pastries, chocolates, chips and coconut. Monounsaturated and polyunsaturated fats from olive oil, canola oil, avocado and nuts are beneficial in small quantities.
- **Salt**: your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table and avoid cooked or processed foods containing high sodium (salt) levels.
- **Exercise**: regular exercise, maintained over the long term, helps to reduce blood pressure and helps get the heart fitter. Regular exercise also improves your blood cholesterol levels, helps reduce your weight and stress levels, and improves your sleep, mood and ability to concentrate. However, it is important not to overdo it. Walking is good exercise, but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of programme for you.
- **Smoking** - your doctor may advise you to stop smoking or at least cut down. There are enormous benefits to be gained from giving up smoking. There are many professionals, organisations and strategies to help you quit. Ask your doctor or pharmacist for further information and advice.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store OLMERTAN COMBI TABLETS below 25°C.

Store OLMERTAN COMBI TABLETS in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking OLMERTAN COMBI TABLETS, or if it has passed the expiry date, ask your pharmacist what to do with any leftover medicine.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

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

OLMERTAN COMBI TABLETS helps most people with high blood pressure, but it may have unwanted side effects in a few people.

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

Hydrochlorothiazide, a component of this medicine, increases sensitivity of the skin to the sun and may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer).

Hydrochlorothiazide, a component of this medicine, may cause a decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).

Hydrochlorothiazide, a component of this medicine, may cause fever, severe shortness of breath, breathing faster than normal, difficulty breathing, slightly blue fingertips and lips.

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

The following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • feeling light-headed, dizzy or faint • cough • headache • feeling sick (nausea) or vomiting • stomach pain • diarrhoea or constipation • an uncomfortable feeling in the stomach • unusual tiredness or weakness, fatigue • 'flu-like' symptoms • runny or blocked nose, or sneezing • bronchitis • sore throat and discomfort when swallowing (pharyngitis) • swelling of the hands, feet or ankles • back pain • urinary tract infection • jaundice • blurred vision • skin rashes or eczema • sleep disturbance • depression <p>The above list includes the more common side effects of your medicine. They are generally mild</p>	<p>Speak to your doctor if you have notice any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • skin rash or itchiness • aching, tender or weak muscles not caused by exercise • painful joints • fast heart beat • shortness of breath or tightness in the chest • swelling of the hands, feet or ankles • yellowing of the whites of the eyes, dark urine and itching of the skin. • symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, change in heart rhythm <p>The above list includes serious side effects that may require medical attention. Serious side effects are rare</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very Serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none"> • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing • chest pain. <p>These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

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 OLMERTAN COMBI TABLETS contains

<p>Active ingredient (main ingredient)</p>	<ul style="list-style-type: none"> • OLMERTAN COMBI TABLETS 20/12.5 - 20mg olmesartan medoxomil and 12.5mg hydrochlorothiazide • OLMERTAN COMBI TABLETS 40/12.5 TABLETS - 40mg olmesartan medoxomil and 12.5mg hydrochlorothiazide • OLMERTAN COMBI TABLETS 40/25 TABLETS - 40mg olmesartan medoxomil and 25mg hydrochlorothiazide
<p>Other ingredients (inactive ingredients)</p>	<ul style="list-style-type: none"> • Lactose monohydrate, • Microcrystalline cellulose, • Hydroxypropyl cellulose, • Magnesium stearate, • Stearic acid • Instacoat Universal A05G11632 yellow (ARTG No. 110035) [for 20/12.5 mg and 40/12.5 mg strengths only] that contains titanium dioxide (E171), talc (E553b),

	<p>hypromellose (E464), polyethylene glycol (E1521), Iron oxide red (E172) and Iron oxide yellow (E172). [for 20mg/12.5mg and 40mg/12.5mg]</p> <ul style="list-style-type: none"> • Instacoat Universal A05G11616 orange (ARTG No. 110036) [for 40/25 mg strength only] that contains titanium dioxide (E171), talc (E553b), hypromellose (E464), polyethylene glycol (E1521), Iron oxide red (E172) and Iron oxide yellow (E172). [for 40mg/25mg]
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Who distributes OLMERTAN COMBI TABLETS?

PHARMACOR PTY LTD
Suite 803, Tower A, The Zenith
821 Pacific Highway
Chatswood NSW 2067
Australia

Australian Registration Numbers:

OLMERTAN COMBI TABLETS 20/12.5
Tablets blister pack – 286101

OLMERTAN COMBI TABLETS 40/12.5
Tablets blister pack – 286095

OLMERTAN COMBI TABLETS 40/25 Tablets
blister pack -286100

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

OLMERTAN COMBI TABLETS does not contain sucrose, tartrazine or any other azo dyes.

What OLMERTAN COMBI TABLETS looks like OLMERTAN COMBI TABLETS come in three strengths and each has a different appearance:

OLMERTAN COMBI TABLETS 20/12.5 TABLETS is a reddish-yellow, round, film coated TABLETS debossed with "A01" on one side & plain on other side.

OLMERTAN COMBI TABLETS 40/12.5 TABLETS is a reddish-yellow, oval, film coated TABLETS debossed with "A002" on one side & plain on other side.

OLMERTAN COMBI TABLETS 40/25 TABLETS is a pink, oval, film coated TABLETS debossed with "A003" on one side & plain on other side.

The Film-coated TABLETS are packed in

- Al / Al blister packs: 10's, 30's TABLETS
- HDPE bottle packs: 30's are packed with a child-resistant closure.

This leaflet was prepared in 12/2022