

# ALYACEN 1/35

## *Ethinylestradiol and Norethisterone*

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### What is in this leaflet

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This leaflet answers some common questions about ALYACEN 1/35.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using ALYACEN 1/35 against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What ALYACEN 1/35 is used for

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ALYACEN 1/35 is a birth control pill commonly known as a “Combined Oral Contraceptive”. It contains both an estrogen (ethinylestradiol) and progestogen (norethisterone) hormone.

Oral contraceptives belonging to this group produce their birth control (or contraceptive) effect by preventing ovulation (the release of an egg from the ovary) during each menstrual cycle. Combined Oral Contraceptives also cause changes to the mucus of the cervix and the lining of the womb which contribute to the contraceptive action.

**Ask your doctor if you have any questions about why ALYACEN 1/35 has been prescribed for you.**

Your doctor may have prescribed ALYACEN 1/35 for another reason. ALYACEN 1/35 is only available on a prescription from your doctor.

This medicine is not expected to affect your ability to drive a car or operate machinery.

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## **Before you use ALYACEN 1/35**

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### ***When you must not use it***

**Do not take ALYACEN 1/35 until you have talked to your doctor:**

- any medicine containing ethinylestradiol or norethisterone
- any of the ingredients listed at the end of this leaflet
- any other similar medicines (such as other oral contraceptives).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take if:**

- you have had a stroke or a heart attack.
- you have or have had inflammation, infection or clotting in any blood vessel(s), including a clot in the lung
- you have or have had liver disease (including tumours of any type), a history of jaundice or cholestatic jaundice of pregnancy, or severe generalised itch in the body during pregnancy, Dubin- Johnson Syndrome or Rotor Syndrome
- you have abnormal vaginal bleeding, the cause of which is unknown
- you are pregnant or suspect that you may be pregnant
- you have cancer or suspected cancer of the breast or sex organs (e.g. cervix, ovaries, endometrium, womb) and known or suspected estrogen-dependent tumours

- you have a family history of breast nodules, fibrocystic disease or have had an abnormal mammograph
- you have sickle cell anaemia
- you have a lipid metabolism disorder such as congenital hyperlipidaemia
- you have diabetes with blood vessel damage
- you have a history of herpes during pregnancy
- you have otosclerosis (an ear disorder) which worsened in past pregnancies
- you suffer from partial paralysis during migraine attacks (hemiplegic migraine).

**Do not take ALYACEN 1/35 if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribarivin as this may cause increases in liver function blood test results (increase in ALT liver enzyme).**

**ALYACEN 1/35 can be restarted approximately 2 weeks after completion of treatment with the combination drug regimen.**

**If you are not certain whether these may apply to you, or you are worried by anything in this list, tell your doctor.**

**Tell your doctor about any existing medical condition as this may be affected by taking the birth control pill.**

Do not take ALYACEN 1/35 if the packaging is torn or shows signs of tampering.

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

**If you are not sure whether you should be taking this medicine, talk to your doctor.**

### ***Before you start to use it***

**Tell your doctor if you are allergic to any foods, dyes, preservatives or any other medicine.**

**You must tell your doctor if:**

- you are a heavy smoker (15 or more cigarettes per day), especially if you are aged over 35 years.

Oral contraceptives increase your risk of having a stroke or heart attack. Smoking, while taking oral contraceptives, further increases this risk.

**Tell your doctor if you have any other health problems, especially:**

- uterine fibroids
- gallbladder disease
- liver, heart or kidney disease
- high blood pressure
- high cholesterol
- diabetes
- epilepsy
- asthma
- migraine or other headaches
- depression
- a disorder of calcium or phosphorus metabolism.

If you have any of these conditions you should have regular check-ups with your doctor to make sure that taking ALYACEN 1/35 is not making these worse.

**Tell your doctor if you have any of the following:**

- recent surgery or trauma
- recently had a baby
- confined to bed rest for long periods.

The risk of developing blood clots in the deep veins of your body, which can break away and block a blood vessel elsewhere in your body, is increased if you take an oral contraceptive in the above situations.

**Tell your doctor if you wear contact lenses and experience a change in vision or intolerance to your lenses.**

Your doctor may refer you to an eye specialist.

**ALYACEN 1/35 contains lactose. If you know that you are intolerant to some sugars, or your doctor has told you so, speak to your doctor before taking it.**

**Tell your doctor if you plan to become pregnant or are breastfeeding.**

Your doctor can discuss the risks and benefits with you.

**If you have not told your doctor about any of the above, tell him/her before you start taking ALYACEN 1/35.**

***Taking other medicines***

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

Some medicines may alter the effectiveness of ALYACEN 1/35. These include medicines such as:

- rifampicin for the treatment of tuberculosis
- antibiotics such as ampicillin, oxacillin, tetracyclines, sulfamethoxazole and trimethoprim
- anti-fungal agents such as griseofulvin
- barbiturates
- medicines for epilepsy such as carbamazepine and phenytoin
- medicines used to treat or relieve the symptoms of allergy (such as hay fever)
- medicines used to treat or prevent pain
- anti-migraine preparations
- phenylbutazone, a medicine used to relieve symptoms of inflammation, including arthritis
- St John's wort, an ingredient found in medicines you can purchase without a prescription from a pharmacy, supermarket or health food shop

**While you are taking these medicines, and for seven days after stopping them, you should use a non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods). If the seven days extend into the inactive light green tablet section, then you should start a new pack on the next day after having taken the last peach active tablet from the current pack. Skip the 7 light green tablets.**

**This is particularly important if you need to take antibiotics or medicines for epilepsy.**

ALYACEN 1/35 may alter the effectiveness of some medicines. These include:

- Medicines for high blood pressure such as guanethidine
- Medicines to prevent blood clots.

**Ask your doctor or pharmacist about how long you need to use additional non-hormonal contraception.**

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking ALYACEN 1/35.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are taking this medicine.

Do not take ALYACEN 1/35, and tell your doctor if you are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribarivin for the treatment of Hepatitis C.

Treatment with ALYACEN 1/35 should be stopped when you are taking this combination of treatment regimen and can be restarted approximately 2 weeks after completion of this treatment.

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## **How to take ALYACEN 1/35**

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

They may differ from the information contained in this leaflet.

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

### ***How to take it***

Swallow one ALYACEN 1/35 tablet with a glass of water.

**Follow the instructions below carefully to ensure birth control reliability.**

### ***When to take it***

**You must take ALYACEN 1/35 every day, regardless of how often you have sex.**

ALYACEN 1/35 will work best if you do not miss any tablets and take it at the same time each day. Taking ALYACEN 1/35 at the same time each day will also help you remember when to take your tablets.

**If you are concerned about this, please speak to your doctor or pharmacist.**

### ***Starting a hormonal contraceptive for the first time***

- To begin ALYACEN 1/35, take your first tablet on the first day of your next period, that is, the day your bleeding begins.

- Take your first tablet from the top row of the blister strip (i.e. the section which contains all the peach tablets). Take the tablet which corresponds to the appropriate day of the week. For example, if your first day of bleeding is on TUESDAY, you should take the tablet marked “TUE” from the top row of the blister strip.
- Continue to take one tablet every day, following the arrows around the strip, until all 21 peach tablets are finished.
- You should then take one light green tablet daily for the next 7 days, following the arrows so that you are taking the correct tablet for the day of the week. Taking these light green inactive tablets helps you to remember to take a tablet every day.

You can expect your period during the week that you are taking these light green inactive tablets. Your protection continues during this week.

- On the day after your last light green tablet, begin the next strip with a peach tablet from the top row of the blister strip that matches the day of the week. Do this even if you are still bleeding.
- You should start your tablets the same day of the week every four weeks.
- Repeat this sequence of tablet taking for as long as birth control is required.

This product is effective from the first day if taken as directed above.

Although spotting and break-through bleeding may occur in some women, these tend to disappear in the majority of patients after the first three to four cycles.

**Make sure you always have a new strip of tablets available, so that you can continue to take the tablets without interruption.**

***Changing from a different oral contraceptive a hormonal contraceptive for the first time***

**If you are switching to ALYACEN 1/35 from another 21 or 28 day oral contraceptive, follow the instructions below carefully.**

**If switching from a 21 day oral contraceptive:**

- Stop taking your current oral contraceptive after you have taken the last active tablet.
- Leave 7 tablet-free days.

- Start the new ALYACEN 1/35 pack on the eighth day by taking a peach active tablet from the top row of the blister strip which corresponds to the day of the week.
- Continue to take one tablet every day until you finish all 21 peach tablets.
- Then take one light green tablet daily for the next 7 days, before starting your new strip.

**You must use an additional, non- hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until a peach tablet has been taken daily for 7 days without a break.**

**If switching from a 28 day oral contraceptive:**

- Stop taking your current oral contraceptive after you have taken the last inactive tablet in the strip.
- Start the new ALYACEN 1/35 pack on the next day by taking a peach active tablet from the top row which corresponds to the day of the week.
- Continue to take one tablet every day until you finish all 21 peach tablets.
- Then take one light green tablet daily for the next 7 days, before starting your new strip.

You must use an additional, non- hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until a peach tablet has been taken daily for 7 days without a break.

***If you vomit or have diarrhoea after taking ALYACEN 1/35***

If you suffer from a stomach upset which results in vomiting or diarrhoea, the effectiveness of ALYACEN 1/35 may be reduced.

**During any period of vomiting or diarrhoea, continue taking ALYACEN 1/35 tablets. Also use a non- hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods), and continue for seven days following the episode of vomiting or diarrhoea. If these seven days extend into the inactive light green tablet section, you should start a new pack on the next day after having taken the last peach tablet of the current pack (i.e. skip the light green inactive tablets)**

**You may not have a period until you finish the second pack.**

If you have vomiting or diarrhoea after taking a light green tablet, do not worry.



### ***If you forget to take it***

If you forget to take ALYACEN 1/35 it may not work as well in protecting you from becoming pregnant.

**Do not try to make up for missed doses by taking more than one tablet at a time.**

**If you miss a peach active tablet:**

**If you are less than 12 hours late in taking your tablet, you should take that tablet at once and then take the next one at your usual time.**

**If you are more than 12 hours late in taking your tablet, do not take it.**

Take the next day's tablet at the usual time and use an additional, non-hormonal method of contraception for the next seven days (such as condoms or a diaphragm, but not the rhythm or temperature methods).

If the seven days extend into the inactive light green tablet section, then start a new pack on the day after taking the last peach active tablet. Take your first tablet from the top row of the new strip, then repeat the sequence of tablet taking for as long as birth control is required. This will mean that you will not have a period until you finish the second pack.

**If you miss more than one peach tablet, contact your doctor for advice on what to do.**

**If you miss a light green (inactive) tablet:**

**Take it as soon as you remember and continue on as before.**

An additional birth control method is not necessary in this case.

If your doctor told you to take ALYACEN 1/35 differently, or you are unclear about the above directions, then you should discuss this with him or her.

**If you have trouble remembering to take ALYACEN 1/35, ask your pharmacist for some hints.**

### ***If you miss a period***

If you have missed a period you may be pregnant.

**Contact your doctor to check if you are pregnant.**

### ***If you take too much (overdose)***

**Immediately telephone your doctor or pharmacist or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ALYACEN 1/35.**

**Do this even if there are no signs of discomfort or poisoning.**

Serious ill effects have not been reported in young children who have taken large doses of birth control pills.

Overdosage may cause nausea or vomiting. This may be followed by vaginal bleeding or breast enlargement in some women.

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## **While you are using ALYACEN 1/35**

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### ***Things you must do***

**Tell all doctors, dentists and pharmacists who are treating you that you are taking ALYACEN 1/35.**

**Tell the hospital doctor that you are taking ALYACEN 1/35 birth control pills if you need to have an operation, or go to hospital in an emergency.**

**If you are about to be started on any new medicine, tell your doctor or dentist and your pharmacist that you are taking ALYACEN 1/35.**

**If you become pregnant while taking ALYACEN 1/35, see your doctor immediately.**

**If you are about to have any blood tests, tell your doctor you are taking ALYACEN 1/35.**

It may interfere with the results of some tests.

**Visit your doctor regularly for check-ups, including a Pap smear.**

A Pap smear can detect any abnormal cells from the cervix, which may develop into cancer. Cervical cancer has been reported to occur more frequently in women who use oral contraceptives.

Your doctor will advise you of the type and frequency of any tests required.

**Perform regular, breast self- examination.**

Examining your breasts for lumps or any changes in size or shape can help you find a breast cancer early. Breast cancer has been found more frequently in women who use oral contraceptives. It is not known whether this increase is caused by the use of oral contraceptives, or if it is due to the fact that users were examined more often, and therefore the breast cancer was detected earlier.

**If you are unsure, ask your doctor about breast self-examination.**

**If you are worried about contracting a sexually transmitted disease (STD) use a barrier contraceptive method.**

ALYACEN 1/35 does not protect against the transmission of STDs such as HIV-AIDS, chlamydia, genital herpes and warts, gonorrhoea, hepatitis B or human papilloma virus. To protect against STDs ask your partner to wear a condom when having sexual intercourse with you.

**Tell your doctor if you feel depressed, think you are retaining water, experience headaches or experience persistent or recurrent irregular bleeding, or your eyes are uncomfortable whilst wearing contact lenses.**

Your doctor will make an assessment of your condition and advise whether or not you should continue to take ALYACEN 1/35.

**Tell your doctor if you are breastfeeding, or are planning to breastfeed.** Small amounts of the drug are found to be excreted into breast milk and there are rare reports of adverse effects on the nursing child, including jaundice.

Your doctor can discuss the risks and benefits involved with you.

### ***Things you must not do***

**Do not take ALYACEN 1/35 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 stop taking ALYACEN 1/35, or change the dosage, without checking with your doctor.**

If you stop taking ALYACEN 1/35 or do not take a tablet every day, without using another form of contraception, you may become pregnant.

### ***Things to be careful of***

Slight breast tenderness or a feeling of sickness may occur in the first few months of use. This usually improves or stops with continued use.

If vaginal irritation or discharge occurs, it may be an indication of yeast infection for which treatment is available from your doctor.

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ALYACEN 1/35.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

It can be difficult to tell whether side effects are the result of taking ALYACEN 1/35 or are side effects of another medicine you are taking

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

You may not experience any of them.

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

***Tell your doctor if...***

**Tell your doctor if you notice any of the following and they worry you:**

- break-through bleeding
- spotting
- gastric or stomach discomforts including nausea, vomiting and diarrhoea
- change in menstrual flow
- change in weight
- retention of fluids
- dark discolouration of the skin
- blotchy discolouration on the face or limbs (which may persist after the tablets have been stopped)
- absence of periods
- breast changes (tenderness, enlargement and secretion)
- headache, dizziness
- mental depression
- fatigue or tiredness

- hair growth or loss of scalp hair
- acne, rashes, itching
- leg cramps
- backache
- vaginal thrush, vaginal irritation, bladder irritation or urinary tract infection
- pre-menstrual-like symptoms
- change in cervical secretions
- suppression of milk production
- change in appetite
- contact lenses becoming difficult to wear.

The above list contains the more common side effects of your medicine.

***Tell your doctor as soon as possible if...***

**Tell your doctor as soon as possible if you notice any worsening of conditions that you may already have such as:**

- porphyria
- gallbladder disease
- kidney disease
- hereditary angioedema (swelling of the face lips, mouth tongue or throat).

Oral contraceptives are associated with inflammatory bowel diseases (ulcerative colitis, Crohn's disease).

See your doctor as soon as possible if you develop bloody diarrhoea, abdominal pain, fever, rectal bleeding, feeling tired, lose your appetite or lose weight. These are some of the symptoms of inflammatory bowel diseases.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

***Go to hospital if...***

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:**

- unexplained or persistent pains in the head, chest, stomach or legs
- gradual or sudden, partial or complete loss of vision
- double vision, or symptoms of severe vision impairment

- eye protrusion, swelling of the eye or eye lesions
- migraine headaches for the first time
- more frequent or severe migraines if you already suffer from them
- breast lumps
- jaundice or yellowing of the skin or eyes, often with fever, fatigue, loss of appetite, dark coloured urine, nausea and vomiting

Taking oral contraceptives may be associated with liver disease including liver cancer.

- rise in blood pressure

You may experience headache, blurred vision or palpitations. Sometimes your blood pressure may rise without you experiencing any of these symptoms. It is important to keep your routine doctor's appointments so that your blood pressure can be checked.

- swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

Whilst these side effects are rare, they are serious. You may need urgent medical attention or hospitalisation.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

### ***After stopping ALYACEN 1/35***

Delays in becoming pregnant may occur after ALYACEN 1/35 therapy is stopped. This is more likely to occur in women whose periods were irregular before using birth control pills.

**See your doctor if you continue to experience difficulties in falling pregnant.**

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## **After using ALYACEN 1/35**

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### ***Storage***

**Keep your tablets in a safe place away from the sight and reach of children.**

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

**Keep your ALYACEN 1/35 tablets in a dry place, at 20°C to 25°C.**

**Do not keep your tablets in the refrigerator.**

**Do not store ALYACEN 1/35 or any other medicine in the bathroom or near a sink.**

**Do not leave it in the car on hot days or on window sills.**

Heat and dampness can destroy some medicines.

### ***Disposal***

**If your doctor tells you to stop taking ALYACEN 1/35 or if the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## **Product description**

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### ***What it looks like***

ALYACEN 1/35 is available in carton packs consisting of three dispensers of tablets (3 months' supply) each with 21 peach, round, flat faced, beveled edged uncoated tablets, debossed with 'A1' on one side and plain on the other; and 7 light green, round, flat faced, beveled edged uncoated tablets debossed with 'A2' on one side and plain on the other.

### ***Ingredients***

Each peach tablet contains:

- Norethisterone 1 milligram (mg)
- Ethinylestradiol 35 micrograms (µg).
- Anhydrous lactose
- Lactose monohydrate
- Corn starch
- FD&C Yellow No. 6

- Silicon dioxide
- D&C Yellow No. 10
- Talc
- Magnesium stearate

Each light green tablet contains:

- Lactose monohydrate
- Microcrystalline cellulose
- Corn starch
- FD&C Blue No. 2
- D&C Yellow No. 10
- Talc
- Magnesium stearate

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## **Sponsor Details**

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ALYACEN 1/35 is supplied in New Zealand by:

ORSPEC Pharma Management Limited  
PO BOX 59013  
Mangere Bridge  
Auckland 2151  
NEW ZEALAND

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## **Date of Preparation**

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This leaflet was prepared on 16 October 2024.