Ref: 1393/150421/1/F

Campral® EC 333mg gastro-resistant tablets

(acamprosate calcium)

Patient Information Leaflet

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 or nurse.
* This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
* If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Campral EC 333mg gastro-resistant tablets but will be referred to as Campral tablets throughout the rest of this leaflet.
'EC' stands for 'Enteric coated' which is a type of gastro-resistant tablet.

What is in this leaflet

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

1 What Campral tablets are and what they are used for

Campral is a medicine which acts on the central nervous system (the brain and the spinal cord).

Campral helps people who are dependent on alcohol to abstain from drinking alcoholic drinks. Campral in combination with counselling will help you not to drink alcohol. It does this by acting on the chemical changes that have taken place in the brain during the years that you have been drinking alcohol. It does not prevent the harmful effects of continuous alcohol abuse.

2 What you need to know before you take Campral tablets

Do not take Campral tablets:
* if you have had an allergic reaction, skin rash, swelling of the face, wheezing or difficulty breathing after taking acamprosate (INN) calcium or any of the other ingredients of Campral (see list of ingredients in section 6) in the past
* if you are pregnant or breast-feeding
* if you suffer from severe kidney disease
* if you suffer from severe liver disease

Warnings and precautions

Tell your doctor or pharmacist before taking Campral tablets.

You should not be drinking when you start Campral treatment. Campral will be less effective if you keep drinking.

If you drink too much alcohol, your body system and in particular your nervous system adapt to the effects of alcohol. When you then suddenly stop drinking you may experience some unpleasant symptoms known as alcohol withdrawal syndrome, which can last up to two weeks.

You should take Campral tablets as soon as possible after the withdrawal period.

Because patients who suffer from alcohol dependence often also suffer from depression it is recommended that you be monitored for symptoms of depression.

This medicine is not recommended for children or elderly.

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

Campral has often been given to patients together with other medicines that are used to treat alcohol withdrawal or maintain abstinence. So far, Campral does not seem to interfere with the effects of other medicines, however if you are prescribed diuretics (water tablets) consult your doctor.

Campral tablets with alcohol
Drinking alcohol while taking Campral does not make you feel sick, however do not drink alcohol at all during your treatment with Campral.
Even if you drink a small amount of alcohol you run the risk of making your treatment fail and you may end up drinking heavily again.

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant, or planning to become pregnant, you should not take Campral tablets without consulting your doctor first.

If you are breastfeeding, you should not take Campral tablets.

Driving and using machines
Campral does not make you sleepy and therefore is not expected to affect your ability to drive or use machines.

Information about sodium content
This medicine contains less than 1mmol sodium (23mg) per dosage unit, that is to say it is essentially 'sodium free'.

3 How to take Campral tablets

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

The recommended dose

If you weigh 60 kg or more:

The usual dose is 6 tablets a day: 2 tablets in the morning, 2 tablets at noon and 2 tablets in the evening with meals.

If you weigh less than 60 kg

The usual dose is 4 tablets a day: 2 in the morning, 1 at noon and 1 in the evening with meals.

Duration of treatment:
It is recommended that you keep taking Campral for one year.

Campral® EC 333mg gastro-resistant tablets

(acamprosate calcium)

Patient Information Leaflet (continued)

If you take more Campral tablets than you should

If you take too many tablets, call your doctor or hospital casualty department immediately. You may experience diarrhoea and have raised blood calcium levels.

If you forget to take Campral tablets

Do not take a double dose to make up for a forgotten dose.

If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Campral tablets
Talk to your doctor before you stop taking the tablets and follow their advice.

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.

If you experience any of the following side effects with Campral tablets, STOP taking the tablets and contact your doctor immediately: A severe allergic reaction, such as angio-oedema (causing large raised marks on the skin and localised swelling, including the face and throat) or anaphylaxis (causing difficulty in breathing with rash, swelling, wheezing and feeling faint).

The following side-effects have been reported:

Very common: may affect more than 1 in 10 people
* diarrhoea

Common: may affect up to 1 in 10 people
* stomach ache
* gas
* feeling sick
* vomiting
* itchy or spotty skin rash
* decreased sexual desire
* impotence
* frigidity

Uncommon: may affect up to 1 in 100 people
* increased sexual desire

Not Known: frequency cannot be estimated from the available data
* allergic reactions including hives, angio-oedema and anaphylaxis (see the beginning of this section)
* blistering rash characterised by patches of skin filled with fluid

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Campral tablets

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not store above 25°C.
Do not take Campral tablets after the expiry date which is stated on the blister or carton labels.
If your doctor tells you to stop taking this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
If your medicine becomes discoloured or show any other signs of deterioration, ask your pharmacist who will advise you what to do.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Campral tablets contain:
The active substance is 333mg acamprosate (INN) calcium.
The other ingredients are: crospovidone, microcrystalline cellulose, magnesium silicate, sodium starch glycolate, colloidal silica dioxide, magnesium stearate, eudragit L30D, talc and propylene glycol.

What Campral tablets look like and contents of the pack
Campral tablets are white, round, enteric coated tablets marked with 333 on one side and plain on the other side.
The tablets are available in blister packs of 168 tablets.

Manufacturer and Licence Holder
This medicine is manufactured by Merck Sante s.a.s, Centre de production, 2 rue du Pressoir Vert, 45400 SEMOY, France and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 15184/1393 Campral EC 333mg gastro-resistant tablets

Campral is a registered trademark of Merck Sante.

Revision date: 15/04/21

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet in a format suitable for you

Ref: 1393/150421/2/F

Campral® EC 333mg gastro-resistant tablets

(acamprosate calcium)

Patient Information Leaflet

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* If you have any further questions, ask your doctor or pharmacist or nurse.
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* If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Campral EC 333mg gastro-resistant tablets but will be referred to as Campral tablets throughout the rest of this leaflet.
'EC' stands for 'Enteric coated' which is a type of gastro-resistant tablet.

What is in this leaflet

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

1 What Campral tablets are and what they are used for

Campral is a medicine which acts on the central nervous system (the brain and the spinal cord).

Campral helps people who are dependent on alcohol to abstain from drinking alcoholic drinks. Campral in combination with counselling will help you not to drink alcohol. It does this by acting on the chemical changes that have taken place in the brain during the years that you have been drinking alcohol. It does not prevent the harmful effects of continuous alcohol abuse.

2 What you need to know before you take Campral tablets

Do not take Campral tablets:
* if you have had an allergic reaction, skin rash, swelling of the face, wheezing or difficulty breathing after taking acamprosate (INN) calcium or any of the other ingredients of Campral (see list of ingredients in section 6) in the past
* if you are pregnant or breast-feeding
* if you suffer from severe kidney disease
* if you suffer from severe liver disease

Warnings and precautions

Tell your doctor or pharmacist before taking Campral tablets.

You should not be drinking when you start Campral treatment. Campral will be less effective if you keep drinking.

If you drink too much alcohol, your body system and in particular your nervous system adapt to the effects of alcohol. When you then suddenly stop drinking you may experience some unpleasant symptoms known as alcohol withdrawal syndrome, which can last up to two weeks.

You should take Campral tablets as soon as possible after the withdrawal period.

Because patients who suffer from alcohol dependence often also suffer from depression it is recommended that you be monitored for symptoms of depression.

This medicine is not recommended for children or elderly.

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

Campral has often been given to patients together with other medicines that are used to treat alcohol withdrawal or maintain abstinence. So far, Campral does not seem to interfere with the effects of other medicines, however if you are prescribed diuretics (water tablets) consult your doctor.

Campral tablets with alcohol
Drinking alcohol while taking Campral does not make you feel sick, however do not drink alcohol at all during your treatment with Campral.
Even if you drink a small amount of alcohol you run the risk of making your treatment fail and you may end up drinking heavily again.

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant, or planning to become pregnant, you should not take Campral tablets without consulting your doctor first.

If you are breastfeeding, you should not take Campral tablets.

Driving and using machines
Campral does not make you sleepy and therefore is not expected to affect your ability to drive or use machines.

Information about sodium content
This medicine contains less than 1mmol sodium (23mg) per dosage unit, that is to say it is essentially 'sodium free''.

3 How to take Campral tablets

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

The recommended dose

If you weigh 60 kg or more:

The usual dose is 6 tablets a day: 2 tablets in the morning, 2 tablets at noon and 2 tablets in the evening with meals.

If you weigh less than 60 kg

The usual dose is 4 tablets a day: 2 in the morning, 1 at noon and 1 in the evening with meals.

Duration of treatment:
It is recommended that you keep taking Campral for one year.

Campral® EC 333mg gastro-resistant tablets

(acamprosate calcium)

Patient Information Leaflet (continued)

If you take more Campral tablets than you should

If you take too many tablets, call your doctor or hospital casualty department immediately. You may experience diarrhoea and have raised blood calcium levels.

If you forget to take Campral tablets

Do not take a double dose to make up for a forgotten dose.

If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Campral tablets
Talk to your doctor before you stop taking the tablets and follow their advice.

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.

If you experience any of the following side effects with Campral tablets, STOP taking the tablets and contact your doctor immediately: A severe allergic reaction, such as angio-oedema (causing large raised marks on the skin and localised swelling, including the face and throat) or anaphylaxis (causing difficulty in breathing with rash, swelling, wheezing and feeling faint).

The following side-effects have been reported:

Very common: may affect more than 1 in 10 people
* diarrhoea

Common: may affect up to 1 in 10 people
* stomach ache
* gas
* feeling sick
* vomiting
* itchy or spotty skin rash
* decreased sexual desire
* impotence
* frigidity

Uncommon: may affect up to 1 in 100 people
* increased sexual desire

Not Known: frequency cannot be estimated from the available data
* allergic reactions including hives, angio-oedema and anaphylaxis (see the beginning of this section)
* blistering rash characterised by patches of skin filled with fluid

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Campral tablets

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not store above 25°C.
Do not take Campral tablets after the expiry date which is stated on the blister or carton labels.
If your doctor tells you to stop taking this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
If your medicine becomes discoloured or show any other signs of deterioration, ask your pharmacist who will advise you what to do.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Campral tablets contain:
The active substance is 333mg acamprosate (INN) calcium.
The other ingredients are: crospovidone, microcrystalline cellulose, magnesium silicate, sodium starch glycolate, colloidal silica dioxide, magnesium stearate, eudragit L30D, talc and propylene glycol.

What Campral tablets look like and contents of the pack
Campral tablets are white, round, enteric coated tablets marked with 333 on one side and plain on the other side.
The tablets are available in blister packs of 168 tablets.

Manufacturer and Licence Holder
This medicine is manufactured by Merck SL, Poligono Merck Mollet Del Valles 08100, Barcelona, Spain and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 15184/1393 Campral EC 333mg gastro-resistant tablets

Campral is a registered trademark of Merck Sante.

Revision date: 15/04/21

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet in a format suitable for you

Acamprosate calcium 333mg gastro-resistant tablets

Patient Information Leaflet

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* Keep this leaflet. You may need to read it again.
* If you have any further questions, ask your doctor or pharmacist or nurse.
* This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
* If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Acamprosate calcium 333mg gastro-resistant tablets but will be referred to as Acamprosate tablets throughout the rest of this leaflet.

What is in this leaflet

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

1 What Acamprosate tablets are and what they are used for

Acamprosate is a medicine which acts on the central nervous system (the brain and the spinal cord).

Acamprosate helps people who are dependent on alcohol to abstain from drinking alcoholic drinks. Acamprosate in combination with counselling will help you not to drink alcohol. It does this by acting on the chemical changes that have taken place in the brain during the years that you have been drinking alcohol. It does not prevent the harmful effects of continuous alcohol abuse.

2 What you need to know before you take Acamprosate tablets

Do not take Acamprosate tablets:
* if you have had an allergic reaction, skin rash, swelling of the face, wheezing or difficulty breathing after taking acamprosate (INN) calcium or any of the other ingredients of Acamprosate (see list of ingredients in section 6) in the past
* if you are pregnant or breast-feeding
* if you suffer from severe kidney disease
* if you suffer from severe liver disease

Warnings and precautions

Tell your doctor or pharmacist before taking Acamprosate tablets.

You should not be drinking when you start Acamprosate treatment. Acamprosate will be less effective if you keep drinking.

If you drink too much alcohol, your body system and in particular your nervous system adapt to the effects of alcohol. When you then suddenly stop drinking you may experience some unpleasant symptoms known as alcohol withdrawal syndrome, which can last up to two weeks.

You should take Acamprosate tablets as soon as possible after the withdrawal period.

Because patients who suffer from alcohol dependence often also suffer from depression it is recommended that you be monitored for symptoms of depression.

This medicine is not recommended for children or elderly.

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

Acamprosate has often been given to patients together with other medicines that are used to treat alcohol withdrawal or maintain abstinence. So far, Acamprosate does not seem to interfere with the effects of other medicines, however if you are prescribed diuretics (water tablets) consult your doctor.

Acamprosate tablets with alcohol
Drinking alcohol while taking Acamprosate does not make you feel sick, however do not drink alcohol at all during your treatment with Acamprosate. Even if you drink a small amount of alcohol you run the risk of making your treatment fail and you may end up drinking heavily again.

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant, or planning to become pregnant, you should not take Acamprosate tablets without consulting your doctor first.

If you are breastfeeding, you should not take Acamprosate tablets.

Driving and using machines
Acamprosate does not make you sleepy and therefore is not expected to affect your ability to drive or use machines.

Information about sodium content
This medicine conatins less than 1mmol sodium (23mg) per dosage unit, that is to say it is essentially ‘sodium free’.

3 How to take Acamprosate tablets

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

The recommended dose

If you weigh 60 kg or more:

The usual dose is 6 tablets a day: 2 tablets in the morning, 2 tablets at noon and 2 tablets in the evening with meals.

If you weigh less than 60 kg

The usual dose is 4 tablets a day: 2 in the morning, 1 at noon and 1 in the evening with meals.

Duration of treatment:
It is recommended that you keep taking Acamprosate for one year.

Acamprosate calcium 333mg gastro-resistant tablets

Patient Information Leaflet (continued)

If you take more Acamprosate tablets than you should

If you take too many tablets, call your doctor or hospital casualty department immediately. You may experience diarrhoea and have raised blood calcium levels.

If you forget to take Acamprosate tablets

Do not take a double dose to make up for a forgotten dose.

If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Acamprosate tablets
Talk to your doctor before you stop taking the tablets and follow their advice.

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.

If you experience any of the following side effects with Acamprosate tablets, STOP taking the tablets and contact your doctor immediately:
A severe
allergic reaction, such as angio-oedema (causing large raised marks on the skin and localised swelling, including the face and throat) or anaphylaxis (causing difficulty in breathing with rash, swelling, wheezing and feeling faint).

The following side-effects have been reported:

Very common: may affect more than 1 in 10 people
* diarrhoea

Common: may affect up to 1 in 10 people
* stomach ache
* gas
* feeling sick
* vomiting
* itchy or spotty skin rash
* decreased sexual desire
* impotence
* frigidity

Uncommon: may affect up to 1 in 100 people
* increased sexual desire

Not Known: frequency cannot be estimated from the available data
* allergic reactions including hives, angio-oedema and anaphylaxis (see the beginning of this section)
* blistering rash characterised by patches of skin filled with fluid

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Acamprosate tablets

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not store above 25°C.
Do not take Acamprosate tablets after the expiry date which is stated on the blister or carton labels.
If your doctor tells you to stop taking this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
If your medicine becomes discoloured or show any other signs of deterioration, ask your pharmacist who will advise you what to do.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Acamprosate tablets contain:
The active substance is 333mg acamprosate (INN) calcium.
The other ingredients are: crospovidone, microcrystalline cellulose, magnesium silicate, sodium starch glycolate, colloidal silica dioxide, magnesium stearate, eudragit L30D, talc and propylene glycol.

What Acamprosate tablets look like and contents of the pack
Acamprosate tablets are white, round, enteric coated tablets marked with 333 on one side and plain on the other side.
The tablets are available in blister packs of 168 tablets.

Manufacturer and Licence Holder
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If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 15184/1393 Acamprosate calcium 333mg gastro-resistant tablets

Revision date: 15/04/21

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Acamprosate calcium 333mg gastro-resistant tablets

Patient Information Leaflet

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- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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What is in this leaflet

1. What Acamprosate tablets are and what they are used for
2. What you need to know before you take Acamprosate tablets
3. How to take Acamprosate tablets
4. Possible side effects
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1 What Acamprosate tablets are and what they are used for

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2 What you need to know before you take Acamprosate tablets

Do not take Acamprosate tablets:
- if you have had an allergic reaction, skin rash, swelling of the face, wheezing or difficulty breathing after taking acamprosate (INN) calcium or any of the other ingredients of Acamprosate (see list of ingredients in section 6) in the past
- if you are pregnant or breast-feeding
- if you suffer from severe kidney disease
- if you suffer from severe liver disease

Warnings and precautions

Tell your doctor or pharmacist before taking Acamprosate tablets.

You should not be drinking when you start Acamprosate treatment. Acamprosate will be less effective if you keep drinking.

If you drink too much alcohol, your body system and in particular your nervous system adapt to the effects of alcohol. When you then suddenly stop drinking you may experience some unpleasant symptoms known as alcohol withdrawal syndrome, which can last up to two weeks.

You should take Acamprosate tablets as soon as possible after the withdrawal period.

Because patients who suffer from alcohol dependence often also suffer from depression it is recommended that you be monitored for symptoms of depression.

This medicine is not recommended for children or elderly.

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

Acamprosate has often been given to patients together with other medicines that are used to treat alcohol withdrawal or maintain abstinence. So far, Acamprosate does not seem to interfere with the effects of other medicines, however if you are prescribed diuretics (water tablets) consult your doctor.

Acamprosate tablets with alcohol
Drinking alcohol while taking Acamprosate does not make you feel sick, however do not drink alcohol at all during your treatment with Acamprosate. Even if you drink a small amount of alcohol you run the risk of making your treatment fail and you may end up drinking heavily again.

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant, or planning to become pregnant, you should not take Acamprosate tablets without consulting your doctor first.

If you are breastfeeding, you should not take Acamprosate tablets.

Driving and using machines
Acamprosate does not make you sleepy and therefore is not expected to affect your ability to drive or use machines.

Information about sodium content
This medicine contains less than 1mmol sodium (23mg) per dosage unit, that is to say it is essentially ‘sodium free’.

3 How to take Acamprosate tablets

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

The recommended dose

If you weigh 60 kg or more:

The usual dose is 6 tablets a day: 2 tablets in the morning, 2 tablets at noon and 2 tablets in the evening with meals.

If you weigh less than 60 kg

The usual dose is 4 tablets a day: 2 in the morning, 1 at noon and 1 in the evening with meals.

Duration of treatment:
It is recommended that you keep taking Acamprosate for one year.

Acamprosate calcium 333mg gastro-resistant tablets

Patient Information Leaflet (continued)

If you take more Acamprosate tablets than you should

If you take too many tablets, call your doctor or hospital casualty department immediately. You may experience diarrhoea and have raised blood calcium levels.

If you forget to take Acamprosate tablets

Do not take a double dose to make up for a forgotten dose.

If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Acamprosate tablets
Talk to your doctor before you stop taking the tablets and follow their advice.

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.

If you experience any of the following side effects with Acamprosate tablets, STOP taking the tablets and contact your doctor immediately: A severe allergic reaction, such as angio-oedema (causing large raised marks on the skin and localised swelling, including the face and throat) or anaphylaxis (causing difficulty in breathing with rash, swelling, wheezing and feeling faint).

The following side-effects have been reported:

Very common: may affect more than 1 in 10 people
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Common: may affect up to 1 in 10 people
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* gas
* feeling sick
* vomiting
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* decreased sexual desire
* impotence
* frigidity

Uncommon: may affect up to 1 in 100 people
* increased sexual desire

Not Known: frequency cannot be estimated from the available data
* allergic reactions including hives, angio-oedema and anaphylaxis (see the beginning of this section)
* blistering rash characterised by patches of skin filled with fluid

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Acamprosate tablets

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not store above 25°C.
Do not take Acamprosate tablets after the expiry date which is stated on the blister or carton labels.
If your doctor tells you to stop taking this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
If your medicine becomes discoloured or show any other signs of deterioration, ask your pharmacist who will advise you what to do.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Acamprosate tablets contain:
The active substance is 333mg acamprosate (INN) calcium.
The other ingredients are: crospovidone, microcrystalline cellulose, magnesium silicate, sodium starch glycolate, colloidal silica dioxide, magnesium stearate, eudragit L30D, talc and propylene glycol.

What Acamprosate tablets look like and contents of the pack
Acamprosate tablets are white, round, enteric coated tablets marked with 333 on one side and plain on the other side.
The tablets are available in blister packs of 168 tablets.

Manufacturer and Licence Holder
This medicine is manufactured by Merck SL, Poligono Merck Mollet Del Valles 08100, Barcelona, Spain and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM PL 15184/1393 Acamprosate calcium 333mg gastro-resistant tablets

Revision date: 15/04/21

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
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