

PATIENT ALERT CARD

(Front cover)

Important Safety Alerts for Patients taking Ambrisentan Accord (ambrisentan)

This card contains important information about Ambrisentan.
Please read this card carefully before starting your treatment with Ambrisentan Accord.

Your name: _____

Prescribing doctor: _____

If you have questions about Ambrisentan Accord ask your doctor.

Date of preparation: February 2020

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRa Pharmacovigilance, Website: www.hpra.ie Side effects can also be reported to Accord Healthcare Ireland Ltd. via
E-mail: medinfo@accord-healthcare.com;
Tel: +44 (0) 1271 385 257; or by completing the online form at www.accord-healthcare.ie/drug-reaction-report

(Inside 1)

If you are a woman of childbearing age read this page carefully Pregnancy

Ambrisentan Accord is teratogenic in animals.
Ambrisentan Accord may harm unborn babies conceived before, during or soon after treatment.

If you are a woman:

- You must not take Ambrisentan Accord if you are pregnant, or if you are planning to become pregnant
- Women of reproductive potential must use reliable contraception whilst taking Ambrisentan Accord
- If you are in any doubt about which contraceptives to use, consult your doctor or a gynaecologist
- A pregnancy test should be taken every month
- If you miss a period, or if you think you may be pregnant, you must tell your doctor straight away

Your monthly pregnancy test schedule:

- | | | |
|------------------------------------|------------------------------------|------------------------------------|
| <input type="checkbox"/> Jan _____ | <input type="checkbox"/> May _____ | <input type="checkbox"/> Sep _____ |
| <input type="checkbox"/> Feb _____ | <input type="checkbox"/> Jun _____ | <input type="checkbox"/> Oct _____ |
| <input type="checkbox"/> Mar _____ | <input type="checkbox"/> Jul _____ | <input type="checkbox"/> Nov _____ |
| <input type="checkbox"/> Apr _____ | <input type="checkbox"/> Aug _____ | <input type="checkbox"/> Dec _____ |

(Inside 2)

Blood Test for Liver Function
Ambrisentan Accord may cause liver injury. It is important to have blood tests to monitor your liver function before starting treatment and at regular intervals during treatment and to check that your liver is working properly.

Date of first monthly test: _____

Your monthly liver blood test schedule:

- | | | |
|------------------------------------|------------------------------------|------------------------------------|
| <input type="checkbox"/> Jan _____ | <input type="checkbox"/> May _____ | <input type="checkbox"/> Sep _____ |
| <input type="checkbox"/> Feb _____ | <input type="checkbox"/> Jun _____ | <input type="checkbox"/> Oct _____ |
| <input type="checkbox"/> Mar _____ | <input type="checkbox"/> Jul _____ | <input type="checkbox"/> Nov _____ |
| <input type="checkbox"/> Apr _____ | <input type="checkbox"/> Aug _____ | <input type="checkbox"/> Dec _____ |

BBBA7054

Ambrisentan 5mg & 10mg Tablets RMM Patient Card - IE

Mock-up

Proof Round

5

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Revised By: G. Worth

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Colours

- | | |
|----------|---|
| 1. Black | ● |
| 2. | |
| 3. | |
| 4. | |
| 5. | |
| 6. | |

Non Printing Colours

- | | |
|------------|---|
| 1. Profile | ● |
| 2. | |
| 3. | |
| 4. | |
| 5. | |
| 6. | |

EU-Artwork-Support@accord-healthcare.com

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