

# The Amiodarone Passport & Patient Handheld Information Booklet

 Information for patients and  
healthcare professionals



Adapted from original document produced by:  
**Sheffield Teaching Hospitals**  
**NHS Foundation Trust**

# Instruction to the Prescribing Physician

Please use the list below as a guide when you are discussing amiodarone as a treatment option with a patient. It is recommended that each point is checked. Once you have completed the list a label (which is in the back of this booklet) can be placed in the medical notes as a record of informed consent.

- benefits
- serious and common side effects
- what to do in the event of a side effect
- how and when to take the medicine
- expected duration of treatment
- arrangements for monitoring

GMC: Good practice in prescribing and managing medicines and devices  
(February 2013)

Name of Healthcare Professional: .....

## Patient given Amiodarone Passport

Date given: .....

**Given by**

Signature: .....

Print name: .....

# Your information

Address: .....

.....

.....

Postcode: .....

Home telephone: .....

Mobile telephone: .....

Hospital number: .....

Name of GP: .....

Address: .....

Postcode: .....

Telephone number: .....

Prescribing Consultant: .....

Date treatment commenced: .....

Reason for therapy: .....

Expected duration of treatment: .....

# How to use this booklet

The booklet provides you with important information about your treatment and contact information for you to obtain further advice. You should take this booklet with you to any GP or hospital appointments.

**There are 2 sections to this booklet:**

## Section A

This includes important information about amiodarone.

## Section B

In this section you will find '*Monitoring Record Sheets*' to help you and your doctor to monitor your amiodarone treatment including blood tests that you will require.

# Contents

page

Introduction	6
<b>Section A - Important information</b>	<b>7</b>
What is amiodarone?	8
Side effects	13
<b>Section B - Monitoring record sheets</b>	<b>15</b>
Amiodarone shared care protocol	16
Amiodarone baseline test record sheet	17
Responsibilities of the primary care clinician	18
Amiodarone monitoring schedule sheets	19

# Introduction

This booklet has been given to you because you are starting to take a medicine called amiodarone.

A doctor, nurse or pharmacist will go through this booklet with you, explain what it all means and answer any questions you may have.

## **Responsibilities of the patient:**

- Read this booklet carefully
- Read the drug information leaflet which comes in your box of tablets
- Ensure your Monitoring Record Sheets are completed as advised
- Consult your GP if you have any concerns about your treatment

## Section A

# Important Information about Amiodarone

## What is amiodarone?

Amiodarone belongs to the group of medicines known as anti-arrhythmic drugs. It is used to control an irregular or rapid heart rate. It acts on the heart cells and slows the electrical signals sent through the heart.

Your doctor will arrange various tests to check for problems that could make the medicine unsuitable for you. Once these tests have been completed the results can be written in the 'Baseline Tests Record Sheet' by you or your doctor for future reference.

## After treatment has started:

During the time you are prescribed amiodarone and for up to six months after stopping amiodarone you will need monitoring at six monthly intervals.

Your GP or hospital doctor will review any symptoms that might occur and arrange your blood tests for you. Please take your book with you to your appointment so the results can be recorded in the booklet.

### 1. How should I take this medicine?

You should take your amiodarone tablets as directed on the label on the box. You usually need to take a higher dose for the first one or two weeks; this is so that the amount of amiodarone which your body needs can build up enough for the medicine to work properly and as quickly as possible. The dosage should then be reduced to a dose which keeps your heart rhythm normal (usually taken once a day).

You should try to take the tablets at the same time each day with a glass of water.

**2. What if I forget to take a tablet?**

If you forget to take a tablet, take one as soon as you remember on the same day. If it is nearly time for your next tablet take that one as usual and do not take the one you missed.

**3. How long should I continue to take the amiodarone tablets?**

You should continue taking the tablets for as long as they are prescribed by your doctor. You should make sure that your medication is reviewed by your doctor at least once every six months.

**4. How should I store my medicine?**

Store your medicine in a cool dry place.

Keep this medicine out of the sight and reach of children.

**5. Where do I get more tablets when these are finished?**

You should be able to get more tablets from your GP.

Make sure you get a new supply before the tablets run out.

**6. Is there any food or drink that I should avoid?**

Do not drink or eat anything containing grapefruit juice whilst taking amiodarone.

## 7. Are there any medicines which I should not take with amiodarone?

Some medicines may not be suitable to take with amiodarone. Please inform your doctor or pharmacist if you are taking any of the following:

Antibiotics *e.g. erythromycin, moxifloxacin, levofloxacin, sulfamethoxazole, co-trimoxazole*  
Anticoagulants  
Antimalarials *e.g. chloroquine*  
Antipsychotics *e.g. amisulpiride, haloperidol*  
Antivirals  
Beta-blockers  
Calcium channel inhibitor *e.g. diltiazem, verapamil*  
Cholesterol lowering “statins” (*maximum dose reductions for atorvastatin and simvastatin*)  
Simvastatin (*maximum dose should be reduced to 20mg*)  
Other cardiac drugs *e.g. flecainide, disopyramide, procainamide, quinidine,*  
Cimetidine  
Ciclosporin  
Diuretics *e.g. furosemide, etc*  
Digoxin  
Ivabradine  
Levothyroxine  
Lithium  
Orlistat  
Pentamidine  
Phenytoin  
Tricyclic Antidepressants *e.g. amitriptyline*

There may be other medicines (including over the counter medicines and oral herbal supplements *e.g. St John’s Wort*) that may not be suitable to take with amiodarone so it is always best to check with your doctor or pharmacist if you are started on a new medicine.

## 8. What should I do if I am already prescribed warfarin or another anticoagulant drug?

### Important notice

You may need to change the dose of warfarin when you start taking amiodarone and also if you stop amiodarone.

#### *Prescribers note for warfarin*

For patients taking warfarin prior to starting amiodarone the warfarin dose should be reduced by approximately one-quarter when amiodarone is started. INR should then be checked weekly for 4 - 6 weeks and until INR is stable. If amiodarone is stopped the effect may persist for up 6 weeks or more, so again INR should be checked weekly until it is stable. Note that amiodarone-induced hyperthyroidism will increase warfarin dose requirements.

## 9. What if I have more questions about amiodarone?

If you need more advice or information, ask your doctor or pharmacist. There are more contact details at the back of this booklet.

## 10. Are there any side effects of this medicine?

*Please also read the drug information leaflet which comes in the box with your tablets.*

If side effects occur, do not stop taking the tablets but tell your doctor as soon as possible.

### Important notice

Amiodarone can cause serious side-effects involving the thyroid gland, liver or lungs.

- If you feel sick (nauseous) for a few weeks or are physically sick (vomit), lose or gain weight or have itchy skin please see your GP.
- Please see your GP immediately if you develop shortness of breath or a persistent cough whilst taking amiodarone.
- You will need to have blood tests before starting amiodarone and then every 6 months, to check for any liver or thyroid problems.

The following page of this booklet describe some of the possible side effects of amiodarone and the likelihood of experiencing problems.

Please note it takes a long time for amiodarone to be removed from the body so problems can occur several weeks or even months after treatment has stopped.

## Very common side effects:

These affect more than 1 in 10 people who take amiodarone

- **Abnormal blood test results.**

**Action:** Your GP will advise you

- **Eye problems.** You may get small deposits in the eye caused by the amiodarone. These are not harmful and usually go away after stopping it. You may notice a blue halo effect when looking at bright lights at night time. If you regularly have your eyes tested, tell the optician that you are taking amiodarone as the deposits will show up on the eye test.

**Action:** If you are worried that you have developed these symptoms please speak to your GP

- **Gastrointestinal problems** including nausea and changes in your sense of taste.

**Action:** If you are worried that you have developed these symptoms please speak to your GP.

- **Photosensitivity skin reactions** with redness, tingling, burning or blistering.

**Avoid:** direct sunlight on your skin or use of sunbeds/sunlamps

**You must:** keep your arms and legs covered, wear a hat and use a total sun block cream whilst in sunlight.

## Common side effects:

These affect more than 1 in 100 people who take amiodarone

- **Liver problems** including jaundice (yellow skin colouring). Some of the liver problems may cause death.

**Action: Seek immediate medical advice.**

- **Lung problems** including breathing difficulties, cough, weight loss, fever or tiredness. Some of the lung problems may cause death.

**Action: Seek immediate medical advice**

**If you think that you have developed any of the following symptoms then you should consult your GP:**

- **Thyroid problems.** You may feel weak, restless, inactive or notice weight changes. Some types of thyroid problems may be fatal.
- **Nightmare and sleeping problems**
- **Extrapyramidal movements.** These are abnormal and involuntary movements.
- **Grey skin colour changes** may occur if amiodarone is taken at a high dose for long period of time.
- **Slower heart rate**

## Section B

# Monitoring Record Sheets

# Amiodarone Shared Care Protocol (SCP)

## Statement of Purpose

The Shared Care Protocol has been written to enable the safe and appropriate continuation of care for patients initiated on amiodarone in hospital. Every patient prescribed amiodarone should be given a handheld record, to promote understanding and ensure adequate monitoring.

The SCP acknowledges that amiodarone is a useful medication but has potentially serious side effects and also that some patients are already prescribed amiodarone in primary care after initial specialist prescription.

## Responsibilities of secondary care doctor

- i. To initiate amiodarone in appropriate patients (see indications)
- ii. To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent.
- iii. To issue the patient hand held book
- iv. To ensure patients are commenced on an appropriate loading and then maintenance dose prior to shared care
- v. To prescribe the first month's supply or a sufficient prescription until the maintenance dose is reached by the patient
- vi. To contact patient's GP to request prescribing under shared care using the amiodarone Transfer of Care (ToC) form and send a link to or copy of the SCP
- vii. To make the baseline test results available to the GP continuing care
- viii. To advise the GP regarding the duration of treatment
- ix. To address any concerns with the GP regarding the patient's treatment.

## Amiodarone baseline test record sheet

Your hospital doctor should arrange for these tests when you start amiodarone. The record sheet can be completed when the test results are available.

Tests	Date	Result	Signature
Liver function		ALT	
Thyroid function		TSH T4	
Chest x-ray			
Pulmonary function tests			

## Responsibilities of the primary care doctor

- i. To refer appropriate patients to secondary care for assessment
- ii. If appropriate, to agree to prescribe in accordance with the SCP by returning the amiodarone ToC form to the referring consultant
- iii. In the event that the GP is not able to prescribe, or where the SCP is agreed but the consultant is still prescribing certain items e.g. hospital only product, the GP will provide the consultant with full details of existing therapy promptly by fax on request
- iv. Where the GP does not prescribe, amiodarone will be added to the practice prescribing system as a hospital only drug
- v. To report any adverse reaction to the Commission on Human Medicines (CHM) and the referring consultant
- vi. To continue to prescribe for the patient as advised by the consultant
- vii. To undertake monitoring as per SCP
- viii. To inform the consultant if the patient discontinues treatment for any reason
- ix. To seek the advice of the consultant if any concerns with the patient's treatment
- x. To conduct a six monthly face to face medication review or more frequent if required

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

## Amiodarone monitoring schedule

These monitoring sheets should be completed at **six monthly intervals** in accordance with the Amiodarone Shared Care Protocol

Symptoms and signs of side effects	Date	Comment	Signature
Cough, breathlessness or fever			
Visual disturbance			
Tests	Date	Result	Signature
Thyroid function		TSH T4	
Liverfunction		ALT	

