Date: **Patient name:**

Hereditary Angioedema Androgen Adverse Event Tracker

This tracker has been developed to help track any adverse events (AEs) your patients experience when taking androgen treatment for hereditary angioedema (HAE), to help you discuss current treatment and other treatment options with your patient. This checklist is available for you to complete with a patient during each appointment. A patient version is also available for you to share with your patient to complete before you next see them.

Please note that the severity of AEs can vary. Please use your clinical judgement to evaluate patient impact and whether specific AEs are a cause for concern.

Guidance for use: ask your patient the list of questions and tick the box if they answer yes. Probe for further information and based on the details they provide, tick the corresponding AE box. For test results, tick any boxes that are relevant following completion of laboratory tests or imaging.

It is important not to review the results in isolation – also take into account efficacy of treatment, patient preferences and other patient factors to decide whether changing treatment should be considered and discussed with your patient.

Comorbidities since starting androgen treatment

Tick all that are applicable

Condition	Tick
Myocardial infarction	
Raised intracranial pressure	
Stroke	
Thrombosis	

Anything else of relevance

Test results	Confirmed AE based on completion of laboratory tests or imaging Where an increase or decrease is mentioned this refers to a change beyond recommended reference ranges since first starting treatment.	Tick
Cholesterol	Decreased HDL levels	
	Increased LDL levels	
Glucose management	Increase in plasma glucagon level (insulin resistance, symptomatic hypoglycaemia)	
	Mild impairment of glucose tolerance in plasma glucose test	
Hepatobiliary	Benign hepatic adenoma	
	Cholestatic jaundice	
	Hepatic failure	
	Hepatocellular focal nodular	
	Hepatocellular injury	
	Hyperplasia	
	Increased serum transaminase levels	
	Jaundice hepatocellular	
	Pancreatitis	

Questions to ask your patient		Suspected or confirmed AE based on information from your patient			
Since starting treatment, have you:	Tick	Adverse Event	Tick	Adverse Event	Tick
Noticed any changes in your pulse? (e.g. very fast or racing heartbeat, skipped beats)		Palpitations		Tachycardia	
Been told of an increase in blood pressure?		Hypertension			
Noticed any heart-related issues? (e.g. chest pain or tightness, shortness of breath)		Arterial thrombosis		Myocardial infarction	
		Cerebrovascular thrombosis		Sagittal sinus thrombosis	
Experienced swelling in your feet or legs?		Fluid retention			
Noticed any changes to your mood or sex drive?		Anxiety		Emotional lability	
		Changes in libido		Nervousness	
		Depressed mood			
Experienced any changes to your skin?		Acne		Seborrhoea	
		Flushing			
Experienced any changes to your hair?		Hair loss		Hirsutism	
[females only] Noticed any changes to your periods or reproductive organs?		Hypertrophy of the clitoris		Menstrual disturbances	
Noticed any differences in your voice?		Voice changes			
Been feeling more hungry than usual or put on weight?		Increased appetite		Weight gain	
Been feeling any stomach pain or sickness?		Epigastric pain		Nausea	
Experienced pain or swelling in your joints/muscles?		Back ache		Joint swelling	
		Increased muscle tremors		Limb pain	
		Joint pain		Muscle cramps	

Visit www.rarediseasehub.co.uk for guidance on strategies for androgen discontinuation

This link will take you to a promotional Takeda UK Ltd website

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

The above side effects were selected for this tracker due to a greater prevalence observed during a Takeda literature review. Please refer to the UK danazol Summary of Product Characteristics for the full list of side effects.

AE, adverse event; HAE, hereditary angioedema; HDL, high density lipoprotein; LDL, low density lipoprotein.

This material is intended for UK healthcare professionals only. September 2024 | C-ANPROM/GB/RDG/0250