Drug Analysis Print
Drug name: THYROID

Jump to first report page

Drug name:	THYROID	**Report type:**	Spontaneous
Report run date:	11-Dec-2012	**Report origin:**	UNITED KINGDOM
Data lock date:	10-Dec-2012 22:52:27	**Route of admin:**	ALL
Period covered:	01-Jul-1963 to 10-Dec-2012	**Reporter type:**	ALL
Earliest reaction date:	21-Nov-2012	**Reaction:**	ALL
MedDRA version:	MedDRA 15.1	**Age group:**	ALL

Total number of reactions*:	2	**Total number of ADR reports:**	1	**Total number of fatal ADR reports:**	0

Products included in this print - Single active constituent products (PBGs):

THIROYD

*It is important to note that one report may contain one or more reactions.

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System Organ Class	Single active constituent		Multiple active constituent		Total unique reports*	
	All	Fatal	All	Fatal	All	Fatal
Cardiac disorders	1	0	0	0	1	0
General disorders	1	0	0	0	1	0

TOTAL NUMBER OF REACTIONS	2	0	0	0	2	0

TOTAL NUMBER OF FATAL ADR REPORTS*		0		0		0*
TOTAL NUMBER OF ADR REPORTS*	1		0		1*	

*This provides the number of individual reports and may be less than the sum of the single-active constituent and multi-active constituent columns. For example, if both a single- and multi-active constituent product are considered by the reporter to have a suspected causal relationship with the suspected reaction, then the same report will appear in both columns.

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Glossary/Abbreviations

ADR - Adverse Drug Reaction

Age group - lists which age groups are included in the Drug Analysis Print – either ALL, Adolescent, Adult, Child, Elderly, Infant or Neonate

Data lock date - shows data on the database at this specified date and time

HLT - High Level Term - see definition of MedDRA

MedDRA - this stands for **Med**ical **D**ictionary for **R**egulatory **A**ctivities, which is the internationally agreed list of terms used for Medicines Regulation. MedDRA groups related adverse drug reaction terms in a hierarchical structure whereby the *'preferred term' (PT)* (e.g. tunnel vision) is grouped under the broader heading the *'high level term' (HLT)* (e.g. visual field disorders). *'High level terms'* are contained within the *'system organ class' (SOC)* (e.g. eye disorders). The *'preferred term'* is the most specific term on the Drug Analysis Print, while the *'system organ class'* is the most general

Multi active constituent products - contain the drug constituent of interest plus one or more other drug constituents (e.g. co-codamol contains paracetamol and codeine)

NEC - appears in MedDRA and stands for Not Elsewhere Classified

NOS - appears in MedDRA and stands for Not Otherwise Specified

PBG - Product Brand Group – this means drug brand name e.g. Amoxil is a PBG for the drug substance amoxicillin

Products included in this print - this is a list of the products for which at least one suspected Adverse Drug Reaction (ADR) report has been received that specifies that product as a 'suspected drug' (i.e. suspected causal association with the reaction). It does not provide an exhaustive list of the products which contain the named drug substance

PT - Preferred Term - see definition of MedDRA

Reaction - defines which ADRs are included in the Drug Analysis Print – either ALL, Serious or Non-Serious

Reporter type - lists the reporter types which are included in the Drug Analysis Print – either Patient, Health Professional or ALL (i.e. both)

Report run date - the date the Drug Analysis Print was produced

Route of admin - lists the route of administration of the suspect drug for which reports are included in the Drug Analysis Print, e.g. ORAL only includes reports where the suspect drug was specified as having been taken by the oral route, or ALL which includes all routes of administration

Single active constituent products - contain only the drug substance of interest

Spontaneous - suspected ADR reports sent in to the Yellow Card Scheme are called spontaneous reports

Substance - is an active ingredient in a product

Substance Variant - is a more specific substance term. A substance may have zero, one or many linked variants. For example LITHIUM is linked to the variant LITHUM CARBONATE and LITHIUM CITRATE.

System Organ Class (SOC) - this is the highest level in MedDRA which groups together reactions that affect similar systems/organs in the body

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
Cardiac disorders						
Supraventricular arrhythmias						
Atrial fibrillation	1	0	0	0	1	0
Cardiac disorders SOC TOTAL	**1**	**0**	**0**	**0**	**1**	**0**

*This provides the number of individual reports and may be less than the sum of the single-active constituent and multi-active constituent columns. For example, if both a single- and multi-active constituent product are considered by the reporter to have a suspected causal relationship with the suspected reaction, then the same report will appear in both columns.

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	Single active constituent		Multiple active constituent		Total unique reports*	
Reaction Name	All	Fatal	All	Fatal	All	Fatal
SOC						
HLT						
PT						
General disorders						
Product quality issues NEC						
Product quality issue	1	0	0	0	1	0
General disorders SOC TOTAL	1	0	0	0	1	0

TOTAL NUMBER OF REACTIONS	2	0	0	0	2	0

TOTAL NUMBER OF FATAL ADR REPORTS*		0		0		0*
TOTAL NUMBER OF ADR REPORTS*	1		0		1*	

*This provides the number of individual reports and may be less than the sum of the single-active constituent and multi-active constituent columns. For example, if both a single- and multi-active constituent product are considered by the reporter to have a suspected causal relationship with the suspected reaction, then the same report will appear in both columns.