

a o p orphan

advanced medicines for individuals

Patient Data Sheet

(Please use codes according to page 2 wherever possible!)

Patient Code		Diagnosis	Essential Thrombocythaemia			Pretherapy with Product	Duration							
Gender		according to PVSG dg.	(x)	WHO 2001/ECP dg.	(x) n.a.	1								
Initials		Year/month of diagnosis				2								
Year/month of birth		Thrombocytes in 10⁹/L				3								
Country		Product				4								
Study participant						5								
Doctor		Y	N	n.t.	Risc factors ****	Y	N	n.t.	Thrombophilic factors ****	Therapy with medication (given under "product" interrupted/terminated)	Comments			
		(x)	(x)	(x)	Adipositas (BMI > 25)	(x)	(x)	(x)	JAK 2 Mutation					
Clinic/Hospital		(x)	(x)	(x)	Smoking	(x)	(x)	(x)	AT III deficiency	Date				
		(x)	(x)	(x)	Hypertension	(x)	(x)	(x)	Prothrombin mutation	Y		N	n.t.	Reason ****
History of MPD related complications ***		(x)	(x)	(x)	Diabetes mellitus	(x)	(x)	(x)	Factor V Leiden mutation	(x)		(x)	(x)	Adverse event
		(x)	(x)	(x)	Cholesterine (mg/dl):	(x)	(x)	(x)	Protein C deficiency	(x)		(x)	(x)	Patients request
(x)	Thrombosis				please insert value	(x)	(x)	(x)	Protein S deficiency	(x)		(x)	(x)	Inefficient therapy
		(x)	(x)	(x)	Triglycerides (mg/dl):	(x)	(x)	(x)	Lupus anticoagulans	(x)		(x)	(x)	Pregnancy
(x)	ET related events				please insert value	(x)	(x)	(x)	APS(Antiphospholipid Antibody Syndrom)	(x)		(x)	(x)	Death
					Other risc factors ****	(x)	(x)	(x)	Factor VIII elevation	(x)		(x)	(x)	Other
(x)	Bleeding				Comment:	(x)	(x)	(x)	Elevated homocystein level	Comment:				
						(x)	(x)	(x)	Fibrinogen					
(x)	other:													

Legend		
*** MPD related complications 1 none Arterial thrombosis (major events) 3 Cerebro-vascular event or Stroke 4 Myocardial Infarction 5 Peripheral arterial disease 6 Other arterial thrombosis Arterial ET related events (minor events) 7 TIA (hemiparesis, dysarthria, aphasia, balance disorders) 8 Angina pectoris 9 Unstable angina 10 Other ET related events Microvascular events 11 Erythromelalgia (other microvascular events) 12 Ocular symptoms (diplopia, scotoma, scotodinia, monocular or binocular blindness, transitory amaurosis) 13 Other peripheral arterial microcirculatory disturbances Venous thrombosis (major events) 14 Iliofemoral venous thrombosis 15 Pulmonary infarction (pulmonary embolism) 16 Splanchnic vein thrombosis (mesenteric infarct) 17 Portal thrombosis 18 Budd Chiari Syndrome 22 Other venous thrombosis (major) Venous ET related events (minor events) 19 Superficial thrombophlebitis 23 Other venous ET related events (minor) Bleeding (major) 20 Hb drop \geq 1 g/dl or RBC transfusion required, Hemorrhagic icterus 24 Other bleeding (major) Bleeding (minor) 21 No RBC transfusion required and Hb drop $<$ 1 g/dl 25 Other bleeding (minor)	* Concomitant Cyto-reductive Therapy TR Thromboreductin HU Hydroxyurea IFN Interferon ** Therapy with Antiaggregants/Anticoagulants 1 none 2 other 3 Aspirin 4 Coumarines 5 Thianopyridin (Clopidrogel, ...) 6 Heparin (other UFH or LMWH) 7 Other antithrombotic drugs *** Risk factors, Thrombophilic factors, Reason for interruption/termination of therapy Y yes N no n.t. not tested **** MPD related complications - Comments A Malignant disorder B Chronic inflammation C Immobility more than 72 hours D Trauma, Polytrauma E Major surgery F Hormon. Contraception, Hormon. Replacement th. G Pregnancy + Thromboreductin treatment ***** Risk factors - other A Malignant disorder B Chronic inflammation C Immobility more than 72 hours D Trauma, Polytrauma E Major surgery F Hormon. Contraception, Hormon. Replacement th.	Instruction A If YES (X), then report on Adverse Drug Reaction Report Form

Patient Data Sheet

Initials																			
Year of birth																			
Follow-up date	Thrombocytes	Hematocrit	White blood cells	Left shift (1-10 Blasts) if applicable	Hemoglobine	Serumcreatinine	ALT (SGPT)	AST (SGOT)	LDH	Urea	Uric acid	Dosage	Concomitant Therapy					Therapy with Antiaggregants/ Anticoagulants **	
	YYYY/MM/DD	10 ⁹ /L	%	10 ⁹ /L	%	g/dl	mg/dl	U/L	U/L	U/L	mg/dl		mg/d	no	other	Product 1 *	Dosage 1		Product 2 *
Date, Signature:																			

Patient Data Sheet

Initials	
Year of birth	

Follow-up date	Substitution of Erythrocytes	Substitution of Thrombocytes	Progression to acute Leucemia	Progression to Agnogenic Myeloid Metaplasia (= Idiopathic Myelo Fibrosis)	Progression to Polycythaemia vera	Splenomegaly	other Disease progressions	MPD related complications ***	Comments****	Adverse drug reaction (in case of adverse drug reaction please fill in the attached form) (see instruction A)	Serious adverse drug reaction (in case of serious adverse drug reaction please fill in the attached form) (see instruction A)	General Comments
YYYY/MM/DD	X	X	X	X	X	X	X	***	*****	X	X	
Date, Signature:												

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Initials																			
Year of birth																			
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YYYY/MM/DD	X	X	X	X	X	X	X	***	*****	X	X	
Date, Signature:												

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YYYY/MM/DD	X	X	X	X	X	X	X	***	*****	X	X	

Date, Signature: