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|  |  |  | advanced medicines for individuals | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| ***Patient Data Sheet*** | | | | | | | | *(Please use codes according to page 2 wherever possible!)* | | | | | | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **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 | | | | | | |  | | | | | | | |  |
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| **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 \*\*\*\*** | | | |  |  |
|  | | | | | | | | | | | | | (x) | (x) | (x) | Diabetes mellitus | | | | | |  | (x) | (x) | (x) | Factor V Leiden mutation | | | | |  | (x) | (x) | (x) | Adverse event | | | |  |  |
| **History of MPD related complications \*\*\*** | | | | | | | | | | | |  |  |
| (x) | | | Thrombosis | | | | | | | | |  | (x) | (x) | (x) | Cholesterine (mg/dl): | | | | | |  | (x) | (x) | (x) | Protein C deficiency | | | | |  | (x) | (x) | (x) | Patients request | | | |  |
|  |  |  |  | please insert value | | | | | |  | (x) | (x) | (x) | Protein S deficiency | | | | |  | (x) | (x) | (x) | Inefficient therapy | | | |  |
| (x) | | | ET related events | | | | | | | | |  | (x) | (x) | (x) | Triglycerides (mg/dl): | | | | | |  | (x) | (x) | (x) | Lupus anticoagulans | | | | |  | (x) | (x) | (x) | Pregnancy | | | |  |
|  |  |  |  | please insert value | | | | | |  | (x) | (x) | (x) | APS(Antiphospholipid Antibody Syndrom) | | | | |  | (x) | (x) | (x) | Death | | | |  |
| (x) | | | Bleeding | | | | | | | | |  | Other risc factors \*\*\*\* | | | | | | | | |  | (x) | (x) | (x) | Factor VIII elevation | | | | |  | (x) | (x) | (x) | Other | | | |  |
|  | Comment: | | | | | | | | |  | (x) | (x) | (x) | Elevated homocystein level | | | | |  | Comment: | | | | | | |  |
| (x) | | | other: | | | | | | | | |  |  | (x) | (x) | (x) | Fibrinogen | | | | |  |  |
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| ***Legend*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
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| **\*\*\* MPD related complications** | | | | | | | | | | | | | | | | |  | **\* Concomitant Cytoreductive Therapy** | | | | | | | | | | | | |  | **Instruction A** | | | | | | | | | | | | | | |  |
| 1 | none | | | | | | | | | | | | | | | |  | TR | Thromboreductin | | | | | | | | | | | |  | If YES (X), then report on Adverse Drug Reaction Report Form | | | | | | | | | | | | | | |  |
| **Arterial thrombosis (major events)** | | | | | | | | | | | | | | | | |  | HU | Hydroxyurea | | | | | | | | | | | |  |  |
| 3 | Cerebro-vascular event or Stroke | | | | | | | | | | | | | | | |  | IFN | Interferon | | | | | | | | | | | |  |  | | | | | | | | | | | | | | |  |
| 4 | Myocardial Infarction | | | | | | | | | | | | | | | |  |  |  | | | | | | | | | | | |  |  |
| 5 | Peripheral arterial disease | | | | | | | | | | | | | | | |  | **\*\* Therapy with Antiaggregants/Anticoagulants** | | | | | | | | | | | | |  |  |
| 6 | Other arterial thrombosis | | | | | | | | | | | | | | | |  | 1 | none | | | | | | | | | | | |  |  |
| **Arterial ET related events (minor events)** | | | | | | | | | | | | | | | | |  | 2 | other | | | | | | | | | | | |  |  |
| 7 | TIA (hemiparesis, dysarthria, aphasis, balance disorders) | | | | | | | | | | | | | | | |  | 3 | Aspirin | | | | | | | | | | | |  |  |
| 8 | Angina pectoris | | | | | | | | | | | | | | | |  | 4 | Coumarines | | | | | | | | | | | |  |  |
| 9 | Unstable angina | | | | | | | | | | | | | | | |  | 5 | Thianopyridin (Clopidrogel, ...) | | | | | | | | | | | |  |  |
| 10 | Other ET related events | | | | | | | | | | | | | | | |  | 6 | Heparin (other UFH or LMWH) | | | | | | | | | | | |  |  |
| **Microvascular events** | | | | | | | | | | | | | | | | |  | 7 | Other antithrombotic drugs | | | | | | | | | | | |  |  |
| 11 | Erythromelalgia (other microvascular events) | | | | | | | | | | | | | | | |  |  |  | | | | | | | | | | | |  |  |
| 12 | Ocular symptoms (diplopia, scotoma, scotodinia, monocular or binocular blindness, transitory amaurosis) | | | | | | | | | | | | | | | |  | **\*\*\*\* Risc factors, Thrombophilic factors, Reason for interruption/termination of therapy** | | | | | | | | | | | | |  |  |
| 13 | Other peripheral arterial microcirculatory disturbances | | | | | | | | | | | | | | | |  | Y | yes | | | | | | | | | | | |  |  |
| **Venous thrombosis (major events)** | | | | | | | | | | | | | | | | |  | N | no | | | | | | | | | | | |  |  |
| 14 | Ileofemoral venous thrombosis | | | | | | | | | | | | | | | |  | n.t. | not tested | | | | | | | | | | | |  |  |
| 15 | Pulmonary infarction (pulmonary embolism) | | | | | | | | | | | | | | | |  |  |  | | | | | | | | | | | |  |  |
| 16 | Splanchnic vein thrombosis (mesenteric infarct) | | | | | | | | | | | | | | | |  | **\*\*\*\*\* MPD related complications - Comments** | | | | | | | | | | | | |  |  |
| 17 | Portal thrombosis | | | | | | | | | | | | | | | |  | A | Malignant disorder | | | | | | | | | | | |  |  |
| 18 | Budd Chiari Syndrome | | | | | | | | | | | | | | | |  | B | Chronic inflammation | | | | | | | | | | | |  |  |
| 22 | Other venous thrombosis (major) | | | | | | | | | | | | | | | |  | C | Immobility more than 72 hours | | | | | | | | | | | |  |  |
| **Venous ET related events (minor events)** | | | | | | | | | | | | | | | | |  | D | Trauma, Polytrauma | | | | | | | | | | | |  |  |
| 19 | Superficial thrombophlebitis | | | | | | | | | | | | | | | |  | E | Major surgery | | | | | | | | | | | |  |  |
| 23 | Other venous ET related events (minor) | | | | | | | | | | | | | | | |  | F | Hormon. Contryaception, Hormon. Replacement th. | | | | | | | | | | | |  |  |
| **Bleeding (major)** | | | | | | | | | | | | | | | | |  | G | Pregnancy + Thromboreductin treatment | | | | | | | | | | | |  |  |
| 20 | Hb drop >= 1 g/dl or RBC transfusion required, Hemoragic ictus | | | | | | | | | | | | | | | |  |  |  | | | | | | | | | | | |  |  |
| 24 | Other bleeding (major) | | | | | | | | | | | | | | | |  | **\*\*\*\*\*\* Risc factors - other** | | | | | | | | | | | | |  |  |
| **Bleeding (minor)** | | | | | | | | | | | | | | | | |  | A | Malignant disorder | | | | | | | | | | | |  |  |
| 21 | No RBC transfusion required and Hb drop < 1 g/dl | | | | | | | | | | | | | | | |  | B | Chronic inflammation | | | | | | | | | | | |  |  |
| 25 | Other bleeding (minor) | | | | | | | | | | | | | | | |  | C | Immobility more than 72 hours | | | | | | | | | | | |  |  |
|  |  | | | | | | | | | | | | | | | |  | D | Trauma, Polytrauma | | | | | | | | | | | |  |  |
|  |  | | | | | | | | | | | | | | | |  | E | Major surgery | | | | | | | | | | | |  |  |
|  |  | | | | | | | | | | | | | | | |  | F | Hormon. Contryaception, Hormon. Replacement th. | | | | | | | | | | | |  |  |
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|  |  |  | advanced medicines for individuals | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| ***Patient Data Sheet*** | | | | | | | | | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Initials | | |  |  | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Year of birth | | |  |  | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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|  |  |  |  | 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 | | | | | | | | | | | | |  |
|  |  |  |  |  | Cytoreductive | | | | | | | | | | | Therapy with Antiaggregants/ Anticoagulants \*\* | |  |
| Follow-up date | | |  |  | no | other | Product 1 \* | | Dosage 1 | | | Product 2 \* | | Dosage 2 | |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| YYYY/MM/DD | | |  | 109/L | | | % | | 109/L | | % | | g/dl | | mg/dl | | | U/L | | U/L | | | | U/L | | mg/dl | | | mg/dl | |  | mg/d | |  |  | \* | |  | | | \* | |  | | \*\* | |  |
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| **Date, Signature:** | | |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
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|  |  |  | advanced medicines for individuals | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| ***Patient Data Sheet*** | | | | | | | | | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Initials | | |  |  | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| ***Patient Data Sheet*** | | | | | | | | | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| ***Patient Data Sheet*** | | | | | | | | | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 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 | | | | | | |  |
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| ***Patient Data Sheet*** | | | | | | | | | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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|  |  |  | advanced medicines for individuals | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| ***Patient Data Sheet*** | | | | | | | | | | | | | | | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Initials | | |  |  | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Year of birth | | |  |  | | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 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 | | | | | | |  |
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