Instruction for use

ProveDye®
Methylene Blue 0,5%

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COMPOSITION:
Each ampoule of PROVEDYE® 0.5% contains 10 mg of **Methylene Blue (Proveblue®)** diluted in 2 ml of water for injection.

INDICATIONS:
Marker for surgical visualisation such as intra operative seal tests, leakage visualisation and delineation of the fistula tract.

CONTRAINDICATIONS:
Do not administer PROVEDYE®:
- in case of known hypersensitivity to the methylene blue or to any other thiazine dyes,
- in case of previous or ongoing treatment with Selective Serotonin Reuptake Inhibitors (SSRIs), bupropion, buspirone, clomipramine, mirtazapine and venlafaxine,
- in case of Glucose-6-Phosphate Dehydrogenase deficiency,
- in case of pregnancy or breastfeeding PROVEDYE® should be avoided.

In case of moderate or severe renal disease patients must be closely monitored.

METHOD OF ADMINISTRATION AND DOSAGE:
The PROVEDYE® 0.5% Methylene Blue sterile solution can be administered:
- Undiluted in local injection,
- In local injection diluted in normal saline solution,
- In oral administration diluted in water.

PROVEDYE® must be used immediately after opening or dilution.
The PROVEDYE® dilution and volume to be administered depend on the destination of the coloration. PROVEDYE® could be diluted until 0.01%. For this, dilute 2 parts of PROVEDYE® 0.5% with 100 parts of normal saline solution or water.
Details on recommendations on method of administration according to the use are presented in section SPECIAL PRECAUTIONS FOR USE

WARNINGS AND PRECAUTIONS:
> PROVEDYE® must be administered by a healthcare professional.
> A preoperative assessment is recommended before using PROVEDYE®
> Protective measures against patient exposure to strong light, including that within instruments such as pulse oximeters should be taken, because there is a risk of cutaneous photosensitivity reaction.
> The wearing of gloves is recommended for users.

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Methylene Blue 0,5%

SPECIAL PRECAUTIONS FOR USE
(to keep in the operative theatre)

PROVEDYE® 0.5% 2 ml - Sterile solution.
Preparation for local or oral administration. Do not inject PROVEDYE® intravenously, subcutaneously, intrathecally, intra-amniotically or intraocularly.
PROVEDYE® may be diluted in water (for oral use only) or in normal saline solution and must be used immediately after opening or dilution. PROVEDYE® could be diluted until 0.01%. For this, dilute 2 parts of PROVEDYE® 0.5% with 100 parts of normal saline solution or water. Any unused product or waste material should be disposed of in accordance with local requirements.

PROVEDYE®	USE	METHOD OF ADMINISTRATION	
ALL SURGICAL DEPART-MENTS	**Bladder leaks visualisation**	Local injection via a urinary catheter (Foley)	200 – 300 ml of diluted ProveDye® solution
	Cysts delineation	Local injection directly into the cyst	0.1 to 0.5 ml of undiluted ProveDye® solution
URO-GYNE-COLOGICAL AND BREAST SURGERY	**Intra-operative delineation of vagino/ utero-vesical or colorecto-vesical fistula tract**	Local injection	200 – 300 ml of diluted ProveDye® solution
	Ureter leaks and anastomosis visualisation during colorectal or vascular surgery	Local retrograde injection via a urinary catheter	Diluted ProveDye® solution
	Visualisation during transaxillar endoscopy in breast surgery	Local injection directly into the infra-mammary fold	1 ml of undiluted ProveDye® solution
	Nipple discharge visualisation	Local injection directly into the breast duct	2 ml of undiluted ProveDye® solution

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> Do not use a damaged ampoule of PROVEDYE®. Do not use PROVEDYE® if the solution is colourless.
> PROVEDYE® must be used immediately after opening or dilution.
> Do not inject PROVEDYE® intravenously, subcutaneously, intrathecally, intra-amniotically or intraocularly.
> PROVEDYE® is for single use only: discard any remaining solution after opening.
> In case of re-use of PROVEDYE®, there is a risk to lose sterility due to potential contamination of the sterile solution (it is considered as a decrease of technical performance).
> PROVEDYE® should be disposed of in clinical waste.

ADVERSE EFFECTS:

> Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain, blue colour of faeces and saliva.
> Hematologic: hemolysis (in glucose-6-phosphate dehydrogenase deficiency, or high doses), methemoglobinemia (after high doses), hyperbilirubinemia.
> Cardiovascular: hypertension, hypotension, arrhythmia, chest pain.
> Body as a whole: profuse sweating.
> Dermal: rash (blue macules, severe burning pain), skin discoloration, urticaria, increased sensitivity of the skin to the light (photosensitivity).
> Nervous system: headaches, dizziness, mental confusion, anxiety, tremor, fever, aphasia, agitation; serotonin syndrome when certain medicines to treat depression or anxiety have been taken.
> Administration site: thrombophlebitis, (resulting from high doses, if not adequately diluted – not more than 350 mg of methylene blue should be diluted in each 500 mL of infusion fluid), necrosis (if extravasation occurs).
> Renal: blue colour of urine.
> Respiratory, thoracic and mediastinal: dyspnea, tachypnea, hypoxia.
> Ophtalmic: mydriasis.
> Immune: anaphylactic reaction.
> Oral administration may cause gastrointestinal disturbances and dysuria.
> Use of methylene blue for endoscopic tattoo has been associated with vascular necrosis, mucosal ulceration, mural necrosis, extramural fat necrosis and inflammatory changes in the colon.

Note to the user

Any serious incident that has occured in relation to the device should be reported to the manufacturer (safety@provepharm.com) and the competent authority of the Member State in which the user is established.

SHELF-LIFE: 36 months.

STORAGE:

Do not refrigerate PROVEDYE® under 8°C.
Do not freeze. Keep the ampoule in the original package to protect it from light.

CONDITIONING:

2 ml ampoules, in packs of 5 or 20 ampoules.

PUBLICATION DATE:

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PROVEDYE®	USE	METHOD OF ADMINISTRATION	
GASTRO-DIGESTIVE SURGERY	**Colon & bile leakage visualisation**	Local injection via a catheter	1 to 20 ml of diluted ProveDye® solution
	Gastric & pancreatic leakage visualisation	Oral administration or via nasogastric tube	Diluted ProveDye® solution
	Intra-operative delineation of anal fistula tract	Local injection directly in the external opening	Undiluted ProveDye® solution
ENT-ENDOCRINE SURGERY	**Parathyroid glands identification**	Local administration	1 ml of undiluted ProveDye® solution
	Temporalis fascia graft visualisation	Local injection directly into the graft	2 ml of undiluted ProveDye® solution
	Tracheo-oesophageal leakage visualisation	Oral administration or via endotracheal tube or oesophageal catheter	Diluted ProveDye® solution
	Intra-operative delineation of trachea-oesophageal fistula tract		

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