

Internal identification field:

Date / PO No. / pharmacotherapeutic follow-up dossier (PTFD) No.

Administrative identification field

Pharmacy: Name, company name, address, tel., fax, e-mail,...

Healthcare professional(s): TAP... Geneviève, Gynaecologist; 4199999999 address, Tel., fax, e-mail,...

Patient: Name, Valérie, address, Tel., e-mail,...

Patient profile:

Biometrics: 33 years old; 161 cm; 59 kg; Body surface area = 1.618m²; BMI = 22.76

Nature of the problem:

NOLVADEX[®] 20 mg

1 tab once daily x 5 days from the 4th day of menstruation

- Question concerning the drug,
- Indication,
- Outside marketing authorisation.

Prescribing physician's intention(s)

In this women suffering from anovular infertility, NOLVADEX can trigger a transient elevation in FSH and LH leading to the development of the follicle and ovulation. (Its anti-oestrogen action on the hypothalamo-hypophyseal axis, leading to blocking of the negative feedback induced by oestrogens, helps to increase LH-RH.)

Pharmaceutical arguments

Argument: NOVALDEX[®] 20 mg (only marketing authorisation indication: breast cancer) is **contraindicated** during pregnancy due to a few mutagenesis and teratogenesis anomalies reported in animals. The long half-life of the drug (up to a fortnight for one active metabolite) must be remembered, implying the presence of the substance in the body for 2 to 3 months after discontinuation of the drug. The indication for induction of ovulation is not recognised in the marketing authorisation, which excludes this proprietary medicinal product from reimbursement by health insurance systems in this indication.

Proposal: CLOMID[®] (?). Mechanism of action similar to that of tamoxifen (triphenylethylene class, cf. Australian studies of 1989 attached) has a marketing authorisation indication in the induction of ovulation in the context of medically assisted procreation.

Decision:

- Maintenance of treatment**

Reference: Article L 162-4 of the Social Security Code, information from Astra Zeneca, BCB (month, year)

Implementation of the decision:**Notification:**

- Pharmaceutical Opinion notified:** Dr TAP...
- Patient not informed

Signing pharmacist:

- Ixe Titular pharmacist 58866A

This Pharmaceutical Opinion format was produced in accordance with the proposal in the [technical specifications](#). IT service companies are free to offer any other format on condition that it follows the order of the required information.