Welcome to Progestin Only Injectables Training

WomanCare GLOBAL academy

WomanCare GLOBAL A COMPANY OF dkt INTERNATIONAL

Introductions

Split into pairs and ask each other:

1. What is your name?
2. Where are you from?
3. What experience do you have with Progestin only injectables?
4. What expectations do you have about this training?

Ground Rules

Purpose of training

- Discuss family planning and contraception WHO definition and importance
- Overview injectable contraception
- Provide information on best practice counselling
- Practice counseling on injectable contraception
- Introduce Injectafem / Medogen*

* Product packaging and brand name may change depending on the market.

Pre-Course Knowledge Test

Family Planning & Contraception

World Health Organization

"Family planning allows individuals and couples to **anticipate and attain their desired number of children and the spacing and timing of their births.** It is achieved through use of contraceptive methods and the treatment of involuntary infertility.

A woman's ability to space and limit her pregnancies has a direct impact on her health and well-being as well as on the outcome of each pregnancy."[1]

[1]World Health Organization Department of Sexual and Reproductive Health and Research (WHO/SRH) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), Knowledge SUCCESS. Family Planning: A Global Handbook for Providers (2022 update). Baltimore and Geneva: CCP and WHO; 2022

Family Planning & Contraception

Contraceptive information and services are fundamental to the health and human rights of all individuals.

According to 2022 estimates, **164 million women** in reproductive age **have an unmet need for contraception.**[2]

Reasons for this include:

- Lack of or limited access to information or to services
- A limited choice of methods
- Fear or experience of side-effects
- Cultural or religious opposition
- Poor quality of available services

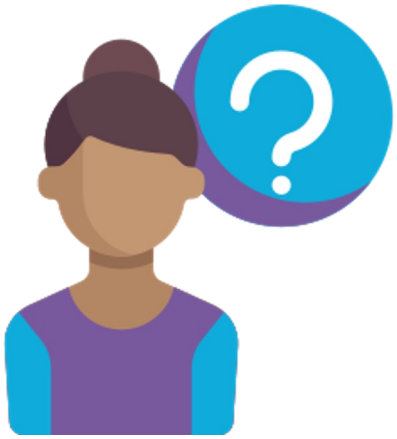
[2] United Nations Department of Economic and Social Affairs. World Family Planning 2022. Meeting the changing needs for family planning: Contraceptive use by age and method. Online: file:///C:/Users/Silvia%20Rivas/OneDrive%20-%20DKTWomanCare.org/Bureau/undesa_pd_2022_WFP%20(1).pdf (Accessed May 12, 2023).

Progestin Only Injectables

Overview

What are POIs?

- Contain a type of hormone called progestogen
  - This is a synthetic equivalent of the natural hormone progesterone
- Releases the hormone progestogen into the bloodstream to prevent pregnancy
  - Injectables 'can' be classified as a type of ***long action reversible contraceptives (LARC),*** that is, methods that are administered at least one month apart
- Short term methods include:
  - Combined oral contraceptive pill which contain synthetic progesterone and synthetic oestrogens
  - Progestogen only pills



Types of LARC

Long action reversible contraceptives (LARC) and injectables

Method	What does it contain?	How does it work?	Approved lifespan	Effectiveness with perfect use
Injectables	Progestogen only	release of eggs from the ovaries (ovulation)	*Replace every 13 weeks (for DMPA)	998 in 1000 women will not become pregnant
Copper IUD	Copper only, no hormones	causing a chemical change that damages sperm and egg before they can meet.	10 years	999 of every 1,000 women using implants will not become pregnant
Levonorgestrel (LNG) IUS	Progestogen only	preventing sperm from fertilizing an egg.	3 – 5 years	998 of every 1,000 women using LNG-IUDs will not become pregnant.
Implants e.g. Levoplant™	Progestogen only	release of eggs from the ovaries (ovulation)	3 years	999 of every 1,000 women using implants will not become pregnant

How do POIs work?

They work by mainly by *inhibiting ovulation*

Also:

- Thickening cervical mucus
- Barrier to sperm entering uterus

Additional precautions are required for **seven days** if the injectable is administered after day one to day five to allow enough time for suppressing ovulation and the mucus having an effect stop.

Types of POI

Type	Lasts for:	Dosing interval	Who can give
DMPA (depo medroxyprogesterone acetate, also known as *Depo Provera*)	13 weeks	Can be given up to 4 weeks late Or 2 weeks early	Intramuscular, needs a trained healthcare provider.
NET-EN (norethindrone enanthate, also known as *Noristerat*)	8 weeks	Can be given up to 2 weeks late Or 2 weeks early	Intramuscular, needs a trained healthcare provider.
Subcutaneous depot Subcutaneous DMPA	13 weeks		Subcutaneous, can be self-administered at home

How effective are POIs?

For perfect use

that is when administered at the correct time interval

998 women in 1000 ***will not*** become pregnant.

That is only 2 women in 1000 will become pregnant (method failure)

If injections are delayed

96 of every 100 women ***will not*** become pregnant.

That is 4 women in 100 will become pregnant (method failure)

Routine Patient Assessment: History

- Age, name, contact information.
- Use of recent medications or herbal remedies, including any medications and the details of their use (dose, route, timing).
- Infection screen.
- Current partner(s) and whether current partner(s) may have other partner(s).
- History or symptoms of any sexually transmitted infections (STIs) including human immunodeficiency virus/ acquired immunodeficiency syndrome (HIV/AIDS).
- Offer HIV testing, STI and cervical cancer screening.
- Take the opportunity to ask about social history. Marital or partner status, family environment, Violence or coercion by partner or family members, Other social issues that could impact her care.
- Obstetric history including the numbers of vaginal deliveries, Caesarean sections, ectopic pregnancies, or any other pregnancy losses.
- Gynaecology history should document if there has been any previous abdominal or uterine surgery.
- Medical conditions and document if she is on any medications including any herbal medications. It is important to ask if she has any allergies.

Routine Patient Assessment:

Physical Examination

- There is no need for a physical examination or blood pressure measurement for women attending for contraceptive services
  - Women should not be denied the injection if these are not available

However, perform testing for STIs or cervical cancer screening for those who request it or where it is clinically indicated.

Contraindication: Definitions

1

What is a contraindication?

Anything (including a symptom or medical condition) that is a reason for a person to not receive a particular treatment or procedure because it may be harmful

2

What is a *relative* contraindication?

When a particular treatment or procedure should be used ***with caution***.

The risk of using the treatment or procedure is acceptable because the benefits outweigh the risks

3

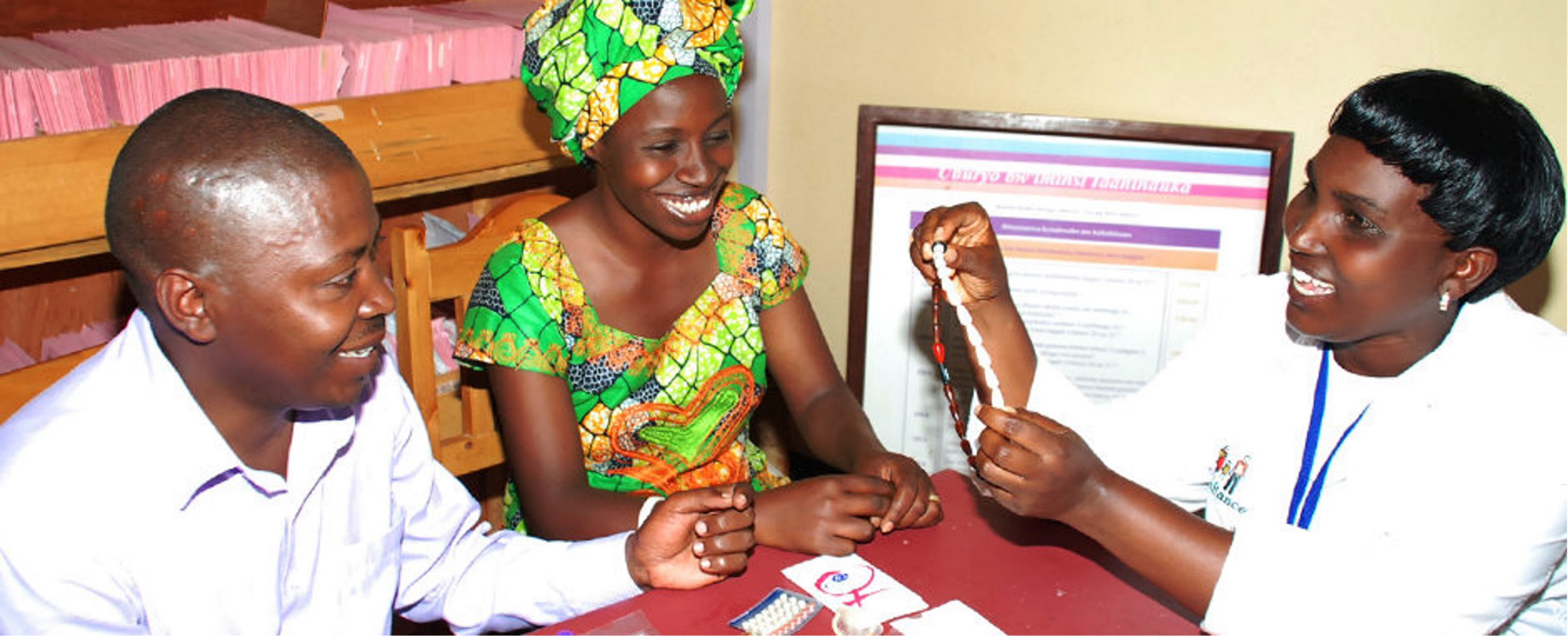
What is an *absolute* contraindication?

When a particular treatment or procedure should not be used under any circumstance because of the severe and potentially life-threatening risks involved

Contraindications: POIs

What is a contraindication?	What is a *relative* contraindication for POIs?	What is an *absolute* contraindication for POIs?
Anything (including a symptom or medical condition) that is a reason for a person to not receive a particular treatment or procedure because it may be harmful	*When a particular treatment or procedure should be used **with caution.*** *The risk of using the treatment or procedure is acceptable because the benefits outweigh the risks*	*When a particular treatment or procedure should not be used under any circumstance because of the severe and potentially life-threatening risks involved.*
	• Suspected pregnancy • Unexplained bleeding in between periods or after sex • Arterial disease or a history of heart disease or stroke • Liver diseases • Breast cancer or have had it in the past • Are at risk osteoporosis	• There are very few **absolute contraindications** to progestogen only contraceptive injection. • Allergies to DMPA or other ingredients.

Counselling



A Rights Based Approach to care

This session is for all staff to gain new skills and refresh any knowledge you already have:

Counselling as part of a Rights-Based Approach

> “Principles of a rights-based approach to service delivery: service users must not only have access to safe, effective, acceptable care – there should be access, equity and availability.”

How can we ensure that the client is getting rights-based care?

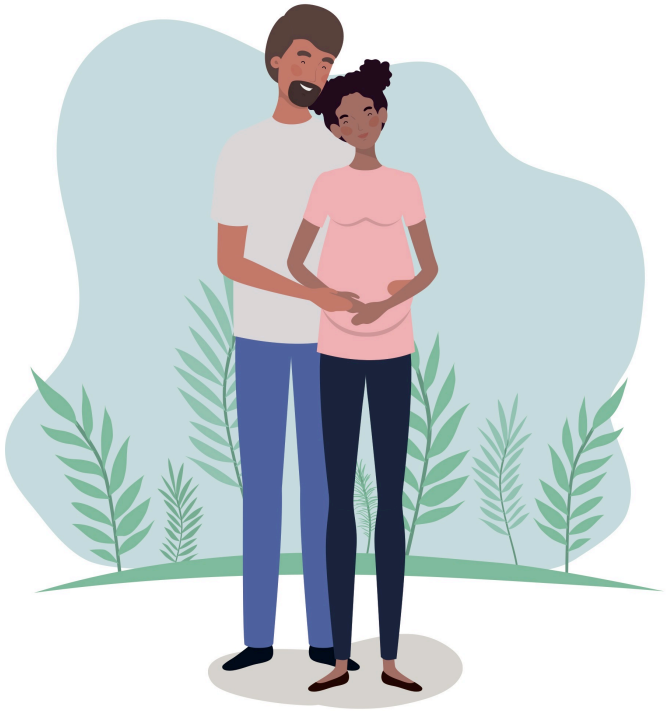
1. Ensuring stock and method mix
2. Importance of contraceptive choice
3. Importance of consent

Rights of patients who attend FP services

- Information
- Access
- Choice
- Security
- Privacy
- Confidentiality
- Comfort
- Follow-up
- Opinion

Characteristics of Balanced Counselling

In Family Planning



- Sexual and reproductive rights
- Communication
- Listen
- Inform
- Clarify doubts

What is Good Counselling?

- Principles of good counselling?
- One well known framework is e.g. EngenderHealth REDI
  - R Rapport Building
  - E Exploring
  - D Decision Making
  - I Implementing the Decision

EngenderHealth
for a better life

What is Good Counselling?

Rapport Building

- Greet client with respect
- Make introductions and identify category of the client (i.e., new, satisfied return, or dissatisfied return)
- Assure confidentiality and privacy
- Explain the need to discuss sensitive and personal issues
- Use communication skills effectively (throughout the phases)

What is Good Counselling?

Exploring

- Identify reason for the visit in detail
- New clients: SRH history, does she want spacing or no more children?
- Return clients: satisfaction with current method, confirm it is being used properly. Does she want spacing or no more children? Discuss existing problems, treating them or switching
- All clients: Focus on the method(s) of interest to the client, addressing individual and other key factors and risk of STIs/HIV

What is Good Counselling?

Decision Making

Summarize from the Exploring phase:

- Identify the decisions the client needs to make or confirm
- Identify relevant options for each decision (e.g., pregnancy prevention, STI/HIV risk reduction)
- Confirm medical eligibility for contraceptive methods the client is considering
- Help the client consider the benefits, disadvantages, and consequences of each option (provide information to address any remaining knowledge gaps)
- Confirm that any decision the client makes is informed, well-considered, and voluntary

What is Good Counselling?

Implementing the Decision

- Assist the client in developing a concrete and specific plan for implementing the decision(s)
- Identify barriers that the client may face in implementing the plan
- Develop strategies to overcome the barriers
- Make a follow-up plan and/or provide referrals, as needed

Importance of Informed Consent

Brainstorm:

What are the principles of informed consent?

THE IMPORTANCE OF INFORMED CONSENT IS TO RECORD THE COUNSELLING PROCESS

Informed Consent

Clients right to make decisions about her own health and welfare

Clients must not be coerced, consent must be voluntary

Clients must have capacity to make decisions for herself and understand risks and benefits

Role Play Counselling and Informed Consent

Let's Play ...

Counselling: Benefits of POIs

- Women do not have to think about contraception or do anything other than attending for repeat injections. They do not interfere with sexual intercourse.
- It is an option for women who cannot use contraception with an oestrogen component such as women at who have heart disease or are at risk of breast cancer.
- Suitable for women of any age.
- It is safe to use when breast feeding after 6 weeks of delivery.
- It is not affected by other medication.
- If a pregnancy occurs while using progestogen only injectables there is no evidence of harm to the foetus. They do not cause abortion.
- IM DMPA can be beneficial for women who are experiencing heavy or painful bleeding or those who are experiencing pain related to endometriosis.
- POIs do not cause cancer.

Counselling: Side effects of POIs

- Changes bleeding pattern are common, and commonly this is means that periods may become lighter or irregular or stop completely.
  - **About 40% of users have no monthly bleeding after 1 year.**
  - This irregular or absent bleeding is not harmful and is not the sign of menopause.
  - Small number of cases bleeding can also become heavier.
  - Can be treated with the combined oral contraceptive pill for 3 months or drugs to reduce bleeding.
- There is an association with weight gain with DMPA particularly in women under 18 years of age who already have a higher body mass index.
- Mood changes, headaches and reactions at injection sites have also been reported.

Injectables do not protect against STIs or HIV

Counselling: Key Points for POIs

Progestogen only injectables are associated with small loss of bone density.

- This loss is recovered after stopping the injections. This may increase the risk of developing osteoporosis and possibly also increase the risk of having bone fractures later, after menopause.

But the WHO has concluded that this decrease in bone density does not place age or time limits on the use of DMPA for women of any age.

Best practice points:

- Women using DMPA should be seen every two years to assess any changes to risks and benefits of continuing with the injections.
- After the age of 50 women are usually advised to switch to another method of contraception. Again a discussion around benefits and risks should take place and the woman further counselled of the risks of reducing bone density.

Counselling: Key Points for POIs

Progestogen only injectables and HIV

- Some studies reported an increase in the risk of acquiring and transmitting HIV when used with progestogen only injectables. There are now **NO** restrictions on use of injectables in these women*
- Importance of dual protection counselling

Fertility

- Delay in return to fertility for several months or up to a year after stopping the any progestogen only injectables.

*Contraceptive eligibility for women at high risk of HIV, World Health Organisation 2019

Progestin Only Injectables

When to start?

Pregnancy Rule-out Checklist

NO	1	Did your last menstrual period start within the past 7 days?	YES
NO	2	Have you abstained from sexual intercourse since your last menstrual period or delivery?	YES
NO	3	Have you been using a reliable contraceptive method consistently and correctly since your last menstrual period or delivery or miscarriage?	YES
NO	4	Have you had a baby in the last 4 weeks?	YES
NO	5	Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then?	YES
NO	6	Have you had a miscarriage or abortion in the past 7 days?	YES

If the client answer ***NO to all of the questions,*** pregnancy cannot be ruled out using the checklist. Rule out pregnancy by other means.

If the client answered ***YES to at least one*** of the questions and she is free of signs or symptoms of pregnancy, you can be reasonably sure she is not pregnant.

When can a woman start POIs?

Circumstances	Starting Day	Additional contraceptive protection required	Any additional information
Women having menstrual cycles	Day 1-7 of cycle After Day 7 of cycle	No Yes (7 days)	It is advisable to check that the menstrual period is typical of the woman's usual bleeding pattern in terms duration, heaviness and timing. If there has been a risk of pregnancy, consider EC
Women who are amenorrhoeic	Any time if it is reasonably certain she is not pregnant	Yes (7 days)	If there has been a risk of pregnancy, consider EC
Postpartum not breastfeeding	≤ 28 days postpartum >28 days if menstrual cycles have returned > 28 days postpartum if menstrual cycles have not returned	No Start as for other women having menstrual cycles Yes (7 days)	If there has been a risk of pregnancy, consider EC and quick starting (see below)
Postpartum breastfeeding or partially breastfeeding	Delay her first injection until at least 6 weeks after giving birth then advise as for non-breastfeeding woman		

When can a woman start POIs?

Circumstances	Starting Day	Additional contraceptive protection required	Any additional information
Post first- or second-trimester abortion	Up to and including Day 7 At any other time if it is reasonably certain she is not pregnant	No Yes (7 days)	The injectable can be initiated after the first part of a medical abortion Ideally start on the day or day after a first- or second- trimester abortion
After taking emergency contraceptive pills (ECPs)	Progestin ECP: Start at the same time UPA ECP: Start or restart injectables on the 6th day after taking UPA-ECPs	Yes (7 days) Yest (7 days) from the time she takes UPA-ECPs until 7 days after the injection.	If she does not start immediately but returns for injectables, she can start at any time if it is reasonably certain she is not pregnant. If she does not start on the 6th day but returns later for injectables, she may start at any time if it is reasonably certain she is not pregnant.

When can a woman start POIs?

Circumstances	Starting Day	Additional contraceptive protection required	Any additional information
Switching from another hormonal method	If she has been using the other hormonal method consistently and correctly or if it is reasonably certain she is not pregnant, she can start immediately.	No	If another method has not been used correctly or consistently, follow as for 'Women having menstrual cycle'.
	If she is switching from another injectable, she can have the new injectable when the repeat injection would have been given.	No	
	If another method has not been used correctly or consistently, follow as for 'Women having menstrual cycle'.	Yes	
Switching from IUD	Start immediately	No	

Progestin Only Injectables

How to Administer

Acceptability of service

To be entirely focused on the patient and her needs

- Create a de-medicalised physical environment; open communication techniques by all staff explaining clearly what she can expect in the waiting room and in the procedure room and afterwards
- A calm physical environment also includes visual and auditory privacy
- Welcoming
- Clean
- Also key to pain control is ‘vocal local’ or verbal anesthesia – from the moment she enters the service until the moment she leaves

Giving the injection

IM DMPA 150mg	IM NET-EN	Subcutaneous DMPA
If available, use a prefilled syringe. Single dose vials can be used with a 2ml syringe and a 21-23 gauge intramuscular needle. If a multidose vial is available, check that is not leaking. Shake the vial gently before use. It is important for the injection to be injected into muscle so the gluteal muscle in the buttock is the preferred site for IM DMPA. In women who have a degree of adiposity in the area consideration should be given to injecting into the deltoid muscle of the upper arm or subcutaneous DMPA because standard length needle may not reach the muscle.	The vial advice is the same as IM DMPA, the difference being using a 2 or 5 ml syringe and 19 gauge needle. Shaking the vial is not necessary. It is a thick, oily fluid which has to be injected very slowly deep into the gluteal muscle. To reduce the viscosity manufacturers, suggest that the ampoule is immersed in warm water before use to reduce viscosity. The viscosity also means that injection with fine needles should be avoided.	Pre-filled injector should be kept at room temperature be administered at room temperature. Shake well before use. It can be injected into the - abdomen, - upper arm or - the anterior thigh.
150 mg medroxyprogesterone acetate in 1 ml in prefilled syringe. Or single dose vial with 2ml syringe and 21-23 gauge IM needle.	Using a 2 or 5 ml syringe and 19 gauge needle.	Pre-filled injector
Must be injected into muscle so the gluteal muscle in the buttock is the preferred site.	Thick, oily fluid which has to be injected very slowly deep into the gluteal muscle	Abdomen, upper arm or the anterior thigh.

Follow-up After POI Administration

There is no medical need for a mandatory routine follow-up unless the woman wishes to be assessed

The exceptions to this are:

- If she thinks she may be pregnant, or her next period is delayed by 7 days. It is recommendation that a pregnancy test be performed in this case.
- If bleeding patterns changes e.g. if bleeding returns after an absence.
- If she would like to stop or change contraceptive method.

Follow-Up

"Come back any time"

Assure every client she is welcome to come back any time, for example, when:

- She has problems, questions, or wants another method,
- She has a major change in health status,
- She thinks she might be pregnant.

Remind her to bring the follow-up card during each visit to the clinic

Documentation

Contemporaneous:

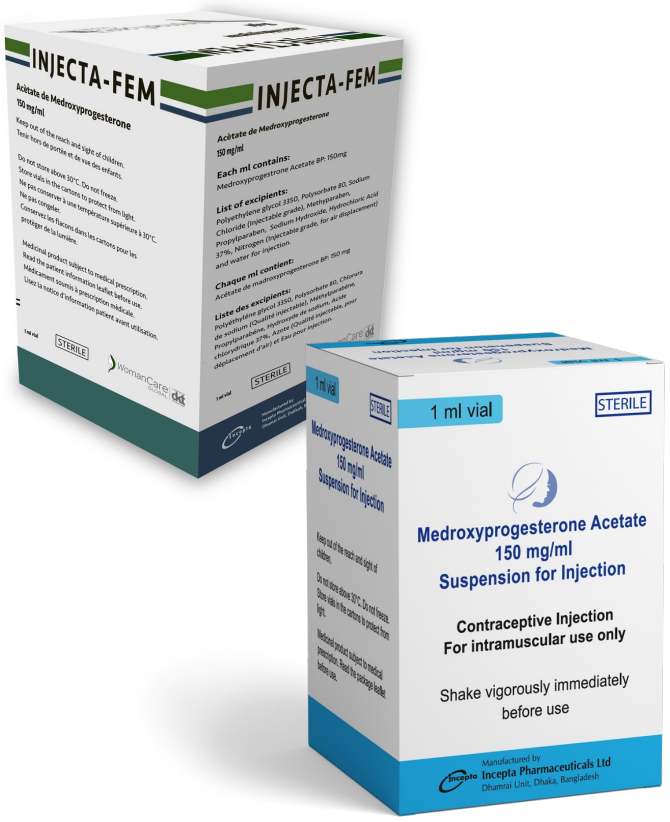
1. All decisions and the rationale for interventions should also be accurately documented together with any drugs administered and procedures carried out.
2. Supports safe and effective care for the patient on the day but contains essential information if she returns with any complication.
3. Data for quality audits.

Injectafem / Medogen

Product Information

INJECTA-FEM

Medogen



Formulation:
150mg of medroxyprogesterone acetate, synthetic equivalent tonatural hormone progesterone.

Duration:
12 weeks (3 months).

Administration:
Intramuscular injection

Approvals:
WHO prequalified

Shelf-life:
3 years.

* Product packaging and brand name may change depending on the market. Two brand names, one same product.

Product overview

Mechanism of Action:

- Inhibiting ovulation
- There is also an effect on survival mucus which can inhibit sperm entering the uterus.
  - This mucosal effect may happen in a few days that can take longer than seven days.
  - Therefore, additional precautions are required for seven days if the injectable is administered after day one to day five to allow enough time for suppressing ovulation and the mucus having an effect stop.

INJECTA-FEM

Medogen

Product overview

INJECTA-FEM

Medogen

Indications

- Long-term contraception in women
- Short-term contraception to cover specific periods

Contraindications & Precautions

- Hypersensitivity to medroxyprogesterone acetate or to any of the excipients
- Known or suspected pregnancy
- History of hormone-dependent cancer
- Abnormal uterine bleeding
- Liver disease
- Hypertension
- Diabetes for longer than 20 years
- History of ischemic heart disease
- History of arterial thrombosis
- Acute deep venous thrombosis or pulmonary embolis
- Systemic lupus erythematosus

¨Patient Information Leaflet

Product overview

INJECTA-FEM

Medogen

Dosage and Administration:

- If available, use a prefilled syringe.
- Single dose vials can be used with a 2ml syringe and a 21-23 gauge intramuscular needle. If a multidose vial is available, check that is not leaking.
- Shake the vial gently before use.
- It is important for the injection to be injected into muscle so the gluteal muscle in the buttock is the preferred site for IM DMPA. In women who have a degree of adiposity in the area consideration should be given to injecting into the deltoid muscle of the upper arm or subcutaneous DMPA because standard length needle may not reach the muscle.
- Injection to be renewed every 12 weeks

Product overview

INJECTA-FEM

Medogen

Side Effects:

- Changes bleeding pattern are common, and commonly this is means that periods may become lighter or irregular or stop completely. In a small number of cases bleeding can also become heavier.
  - These bleeding irregularities can also carry on after stopping the injections. If women find the irregular bleeding problematic they can take three months of the combined oral contraceptive pill if they are eligible or 500 mg mefenamic acid up to three times daily for up to 5 days. This irregular or absent bleeding is not harmful and is not the sign of menopause.
- There may be a delay in return to fertility for several months or up to a year after stopping the any POI injections.
- An association with weight gain with IM or SC DMPA particularly in women under 18 years of age with a body mass index (BMI) ≥30 kg/m2.
- Mood changes, headaches and reactions at injection sites have also been reported.

Questions, Comments, Or Concerns?

We want to hear about it ...

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Email:
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www.dktwomancare.org

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Sources

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