#### **TITLE: Improved GONAL-f® Prefilled Pen**

#### **PAGE:** 1/8

#### **PANEL:** 01-06

#### How to use your GONAL-f<sup>®</sup> prefilled pen.

This video is intended to be viewed by patients who have been prescribed GONAL-f<sup>®</sup>.

Before using your pen, please watch this video all the way through and read the leaflet that is provided in the pack with your pen.



Home Screen.



VO: Hi, that's me Rachel in the picture there, with my husband, Tom. We've been trying for a baby for a little while now, but recently we decided to try IVF... Like you, I've just been prescribed GONAL-f<sup>®</sup>. ACTION: Camera shows bedside table with photos of woman and her partner in frame (stock shot of partner).



your pack with your pen. her en suite bathroom.

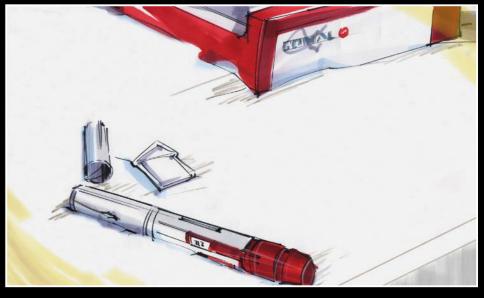


ACTION: We see Rachel drying her hands and the screen blurs. On-screen graphic appears.



VO: But before you get started, make sure you've washed your hands properly, just like I did.

ACTION: We see Rachel walking in to the bedroom.



for your injection...

VO: Today I want to show you how to inject yourself using the GONAL-f® prefilled pen. You'll see that it can be quite easy! As well as watching this video, make sure you read the leaflet that comes in

ACTION: Camera pans round to show Rachel washing her hands in

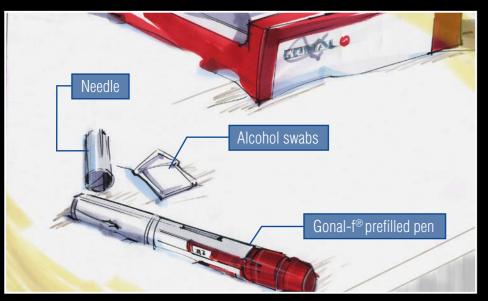
VO: You'll also need to make sure you have all the things you need

ACTION: Rachel opens up the box and takes out her pen, needle and swabs and lays them out on the bedside table.

### TITLE: Improved GONAL-f<sup>®</sup> Prefilled Pen

### **PAGE:** 2/8

## **PANEL:** 07-12



VO: ...the GONAL-f<sup>®</sup> prefilled pen; alcohol swabs; and a needle. ACTION: On-screen graphic appears.



VO: If you're keeping your pen in the fridge, it's best if you take it out about half an hour before you want to inject to let it get to room temperature.

ACTION: We see Rachel pick up her pen and look at it.





VO: Before you use the pen, make sure you check the expiry date. First, take off the pen cap, and take a close look at the solution in the drug reservoir.

ACTION: We see Rachel check the expiry date then take the pen cap off.



VO: The solution should be clear with no particles in it. You must not use it if it isn't clear or if it contains particles. ACTION: Then we see a close up of the drug reservoir.



VO: That will make it a bit more comfortable when you inject! ACTION: Background blurs. On-screen graphic appears.

ACTION: Background blurs. On-screen graphic appears.

### TITLE: Improved GONAL-f<sup>®</sup> Prefilled Pen

### **PAGE:** 3/8

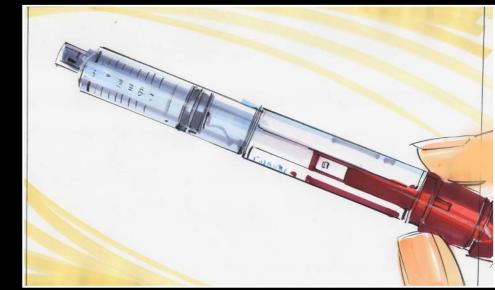
## **PANEL:** 13-18



VO: OK, so mine looks fine! ACTION: Clear close up of Rachel holding the pen.



ACTION: We see a close up of Rachel holding the pen. Background blurs. On-screen graphic appears.



VO: Before attaching the needle, first check that the dose is at zero. ACTION: We see Rachel checking the dose.



VO: And check that the seal on the outer needle cap is in tact. If it's damaged or loose, you should dispose of this needle and use a new one. If the seal is all OK, simply peel it off.

ACTION: She checks the seal and removes it from the outer needle cap.



VO: Then put the threaded end of the pen into the outer needle cap. You'll need to screw it in until it's firmly locked in place. Not too tight though, or it might be hard to take it off again.

ACTION: Attaches and screws the needle in place.



VO: Then pull off the outer needle cap. Keep it handy though, as you'll need it later. And now, remove the green inner needle shield. ACTION: She then removes the needle cap and places on bedside table.

### TITLE: Improved GONAL-f<sup>®</sup> Prefilled Pen

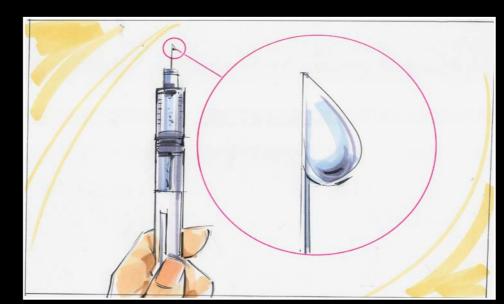
#### **PAGE:** 4/8

## **PANEL:** 19-24



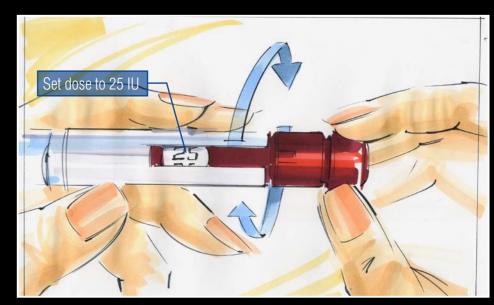
VO: Before using your pen for the first time, you'll need to make sure there's no trapped air.

ACTION: We see Rachel's hand, holding pen upright. Background blurs. On-screen graphic appears.



VO: To do this, look carefully at the tip of the needle for a tiny drop of fluid. If you can see one, then there shouldn't be any air trapped and your pen is ready to use. You can then skip straight to the next step to see how to set the dose.

ACTION: Picture becomes magnified to clearly show the drop of fuild at the tip of the needle.



VO: If you can't see a drop of fluid, you'll need to do a few simple things to remove the trapped air. First you need to set the dose to 25 units by turning the red dose-setting knob. ACTION: We see a close up of her hands holding the pen as she sets her dose. On-screen graphic appears.

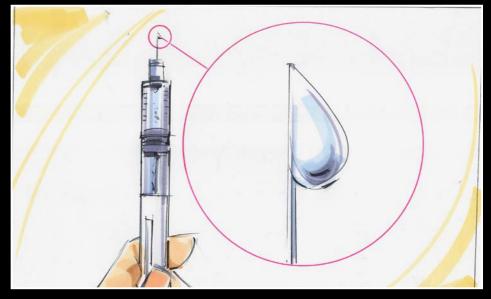


VO: Then as you hold the pen with the needle pointing upwards, like I am here, just gently tap on the drug reservoir. Like this. ACTION: We see the pen held upright with needle pointing upwards, while Rachel taps on side to remove bubbles. On-screen graphic appears.



VO: While still keeping the pen upright, push the dose-setting knob in fully, until the dial returns to zero

ACTION: Camera pans out to show Rachel's face, looking at her needle as she pushes the dose setting knob in. On-screen graphic appears.

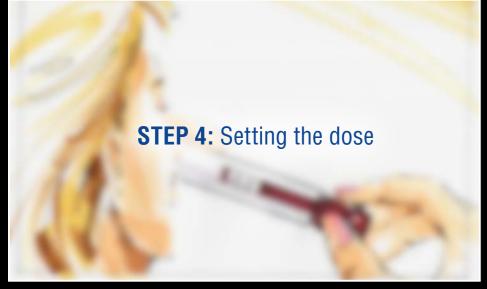


VO: You should be able to see a small drop of fluid, like this one, at the tip of the needle. This means that you've removed all the air. If you still can't see a drop of fluid, you will need to repeat these steps until you see one. Don't worry there is always a bit of extra fluid in the pen so you will have enough for your dose. ACTION: Picture becomes magnified to clearly show the drop of fuild at the tip of the needle.

### TITLE: Improved GONAL-f<sup>®</sup> Prefilled Pen

### **PAGE:** 5/8

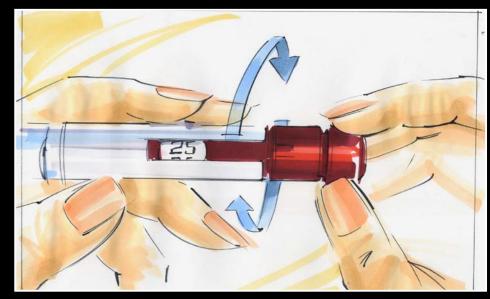
## **PANEL: 25-30**



VO: So, now we're ready to set the dose! ACTION: We see a blurred image of Rachel's hands turning dosesetting knob in the background. On-screen graphic appears.



VO: All you need to do is turn the red dose-setting knob until your prescribed dose appears in this window here on the side of the pen. ACTION: Screen becomes clear to show Rachel's hands turning dose-setting knob.



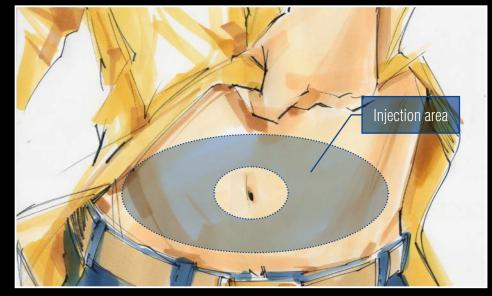
until you get the right dose. display window.



VO: Make sure you double check that the dose you've set is the one prescribed by your doctor before you inject yourself. ACTION: Screen blurs. On-screen graphic appears.



ACTION: Screen blurs. On-screen graphic appears.



ACTION: We see Rachel pull up her top. On-screen graphic appears.

VO: Don't worry if you go past it, you can turn it back the other way

ACTION: Camera pans in close up to the dose window. On-screen graphics show it can be turned both ways and highlights dose

VO: Your doctor or nurse will have talked to you about how and where on your body you should inject. It's best to choose a different injection site each day, so it doesn't become uncomfortable for you.

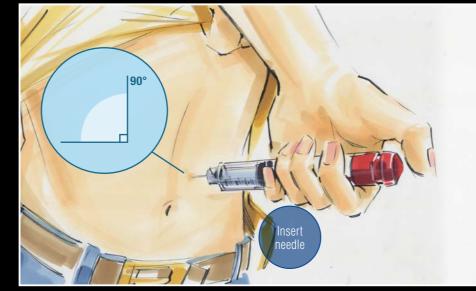
## TITLE: Improved GONAL-f® Prefilled Pen

### **PAGE:** 6/8

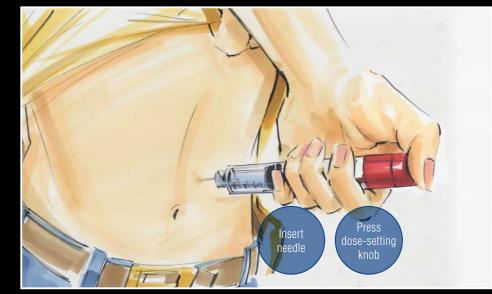
**PANEL: 31-36** 



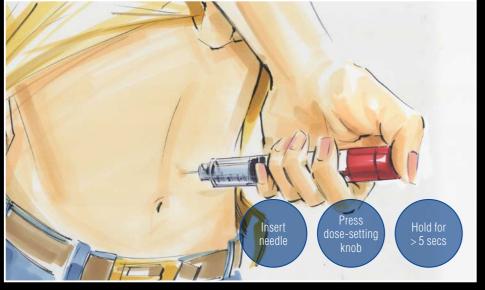
VO: You'll need to clean your skin with an alcohol swab, in the place where you're going to inject. You can let it dry in the air. ACTION: Rachel cleans a small area of her abdomen with a swab.



VO: Now we're ready to inject... There we go, it's in... Just like that! ACTION: A hand appears in view, holding her pen and inserting needle. On-screen graphic appears.



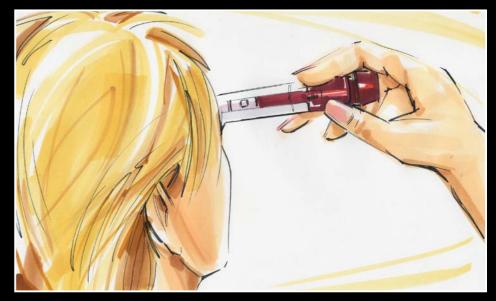
knob down... graphic appears.



VO: ...and keep it pressed down for at least 5 seconds. And when you're done, take the needle out, making sure you keep pressing the red knob down until you've taken the needle out completely. ACTION: We see her holding the knob down for 5 seconds then removing the needle. On-screen graphic appears.



VO: And that's it, all done! So now just press down on the site of your injection with an alcohol swab or cotton pad for a few seconds. ACTION: We see a hand applying pressure to skin with an alcohol swab.



Like mine here, see.

VO: When you've inserted the needle, just push the red dose-setting ACTION: We see her pressing down on the red knob. On-screen

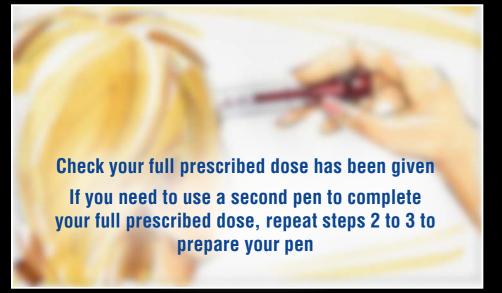
VO: Now you've finished your injection, you'll need to make sure that you injected your full dose. The dose window should show zero.

ACTION: We see Rachel hold up her pen and look at the dose display. We see a close up of the dose window, reading '0'.

### TITLE: Improved GONAL-f<sup>®</sup> Prefilled Pen

### **PAGE:** 7/8

# **PANEL:** 37-42



VO: Sometimes the display may show a number higher than '0'. This means the pen has run out of solution and the full prescribed dose hasn't been given. The number shown is the missing amount that you'll then have to inject using a new prefilled pen. If that happens, prepare a new pen like I've just shown you, and set the dose to the exact number displayed on the dose window of the empty pen. And then do a new injection.

ACTION: Screen blurs. On-screen graphic appears.



VO: Now you've finished, you just need to take the needle off and put the pen away. First put the outer needle cap on a flat surface. Then holding your pen with one hand, very carefully push the needle into the outer needle cap. Push it against a firm surface, like this, until you hear it click.

ACTION: We see her put the outer needle cap on bedside table and push the pen into the cap. On-screen graphic appears.

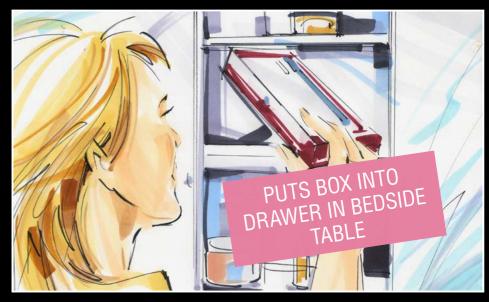




VO: You can then throw away the needle cap with the used needle inside. ACTION: She then puts the needle into a sharps bin.



ACTION: Screen blurs. On-screen graphic appears.



VO: After it's clicked into place, pick up the outer needle cap and unscrew the needle, by turning it anticlockwise. ACTION: Rachel unscrews the needle. On-screen graphic appears.

VO: Now, you can put the pen cap back onto the pen and store it in a safe place away from sunlight, or in the fridge if you prefer. ACTION: Rachel puts the pack away in a bedside table drawer.

# TITLE: Improved GONAL-f® Prefilled Pen

#### **PAGE:** 8/8

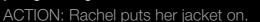
## **PANEL:** 43-46



ACTION: Screen blurs. On-screen graphic appears.



VO: IVF can feel like a bit of a rollercoaster at times, and you might even feel overwhelmed. But as you can see, injecting your GONAL-f<sup>®</sup> can be quite easy, and it tends to get even easier as you go along.





If you have any other questions about how to use your GONAL-f<sup>®</sup> prefilled pen, please ask your doctor or nurse for advice.



ACTION: Fade to logos and copy.

ADR Reporting, The Medicines Authority, Post-licensing Directorate, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta

> Website: www.medicinesauthority.gov.mt E-mail: postlicensing.medicinesauthority@gov.mt

ADR Reporting www.medicinesauthority.gov.mt/adrportal

VO: Thanks for watching. Stay positive. Hopefully your treatment will help you to fulfil your dream of having a family. ACTION: She picks up her notebook and bag and leaves.

> MT/02/2016 - XX/XX/2016 2015-11-CVIA-A3VK38