



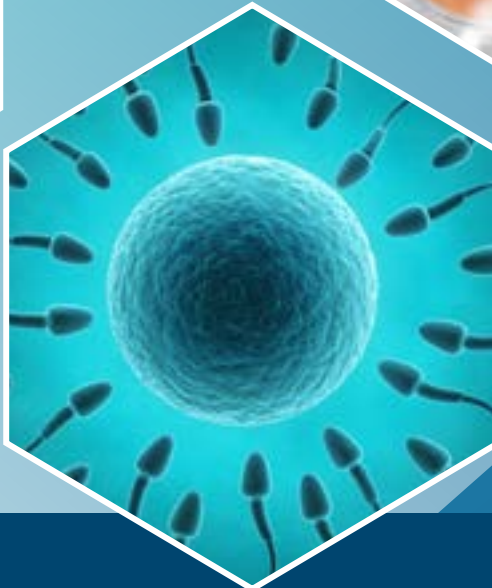
Highly effective new treatment for:

Sub-fertility in women

Polycystic Ovary Syndrome (PCOS)

Sub-fertility in men

Prevention of GDM



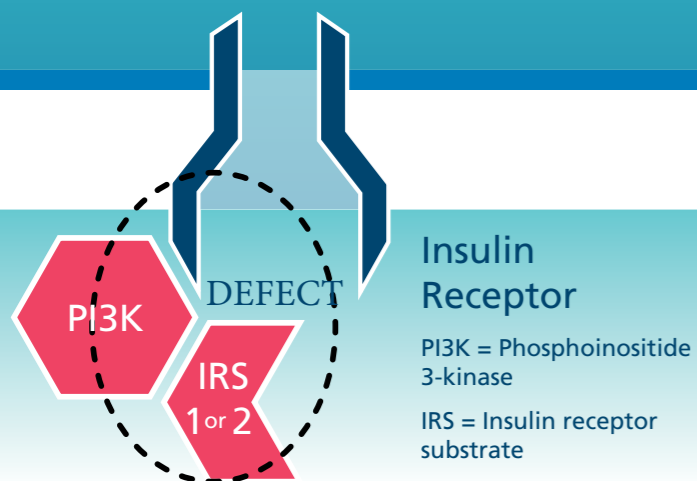
Conceiving Ideas for Generations to Come



Replenitol is a new, highly effective treatment that supplements a biochemical deficiency associated with subfertility and PCOS

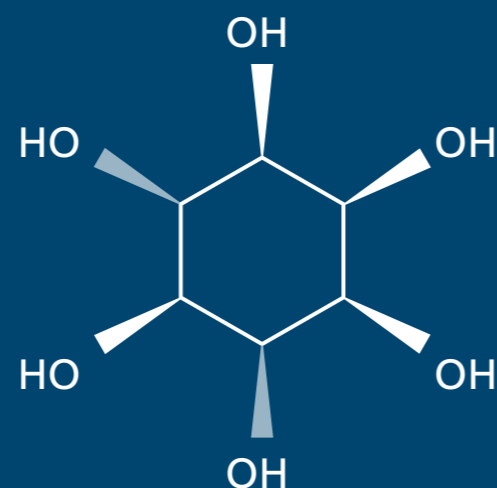
- Myo-inositol is essential for maintaining normal insulin sensitivity, hormone and lipid regulation. It is also highly concentrated in follicular and epididymal fluid.^{10,11,12}
- Women with PCOS and people with diabetes excrete significantly more myo-inositol in their urine which can be measured simply and accurately correlated with blood sugar.^{6,7,8,9}
- 65-80% of women with PCOS have Insulin Resistance.^{1,2}
- Similar proportion of men have a biochemical profile characteristic of PCOS and may have depletion of myo-inositol in the epididymal fluid.^{3,4,5}
- Replenitol supplements a myo-inositol deficiency in follicular and epididymal fluids, normalises insulin resistance and reverses dyslipidaemia.

Site of Defect in at least 50% of women with PCOS¹³



Adapted from Diamanti-Kandarakis E & Dunaif A, 2012

The defect can be reversed by supplementing a metabolic deficiency with a simple substrate, myo-inositol.

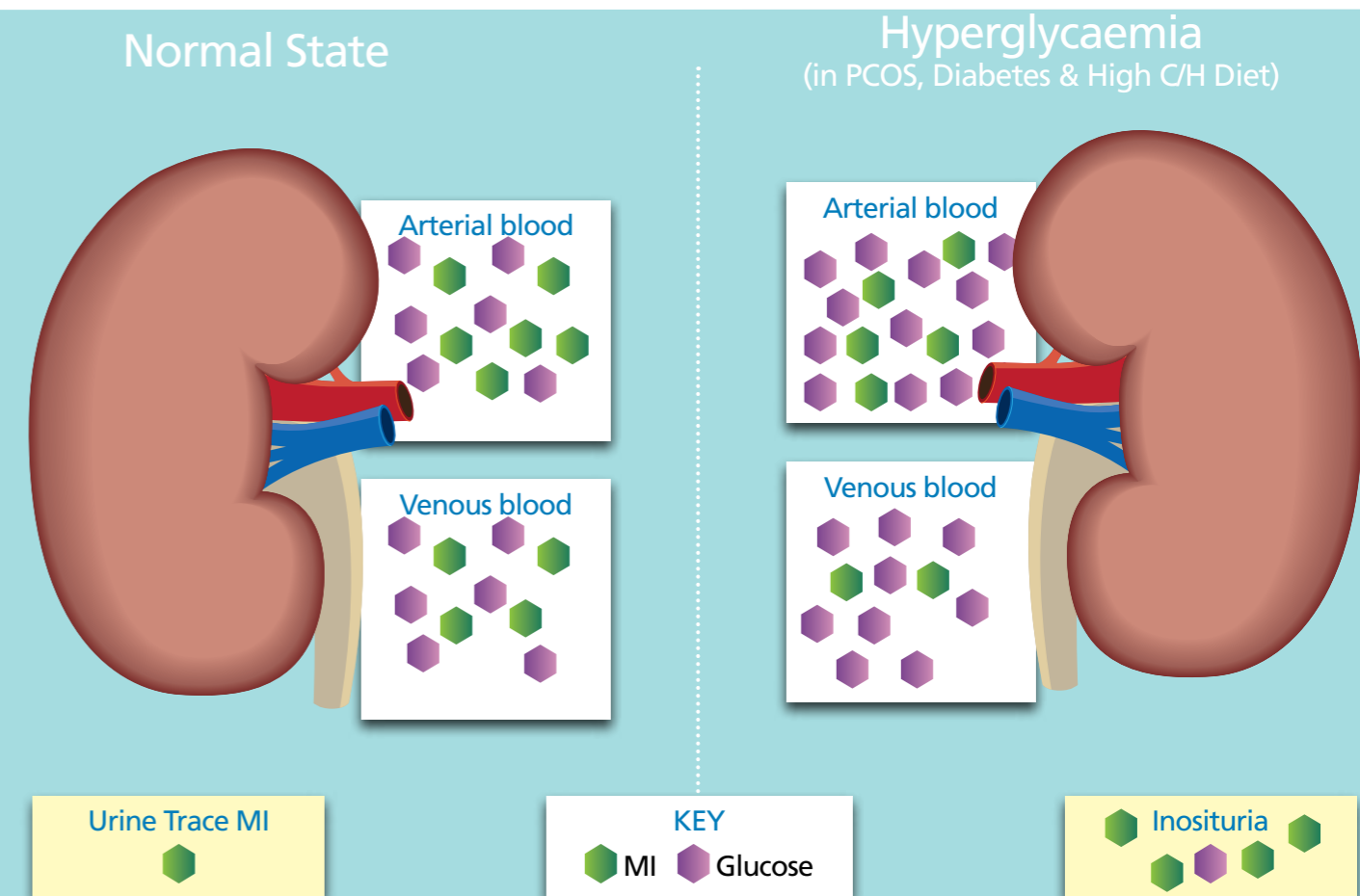


Subfertility associated with myo-inositol depletion can be reversed by taking 2 tablets of Replenitol twice daily.

No side effects in any studies at the recommended dose & no known interactions¹⁴

Inositoria, the excessive excretion of inositol in the urine, is a cardinal sign of PCOS and diabetes

Replenitol replenishes the lost myo-inositol



Arterial blood is filtered by the kidneys.

Almost 100% of glucose and myo-inositol enter the filtrate - both are actively reabsorbed.

Under normoglycaemic conditions, the activity levels of the sodium myo-inositol transport type 2 (SMIT2) co-transporters is normal and ≈100% is reabsorbed.

Glucose is a precious resource - maintaining circulating glucose is a priority.

In hyperglycaemia SMIT2s become inundated with glucose thereby reducing the reabsorption capacity of SMIT2 activity for myo-inositol reabsorption.

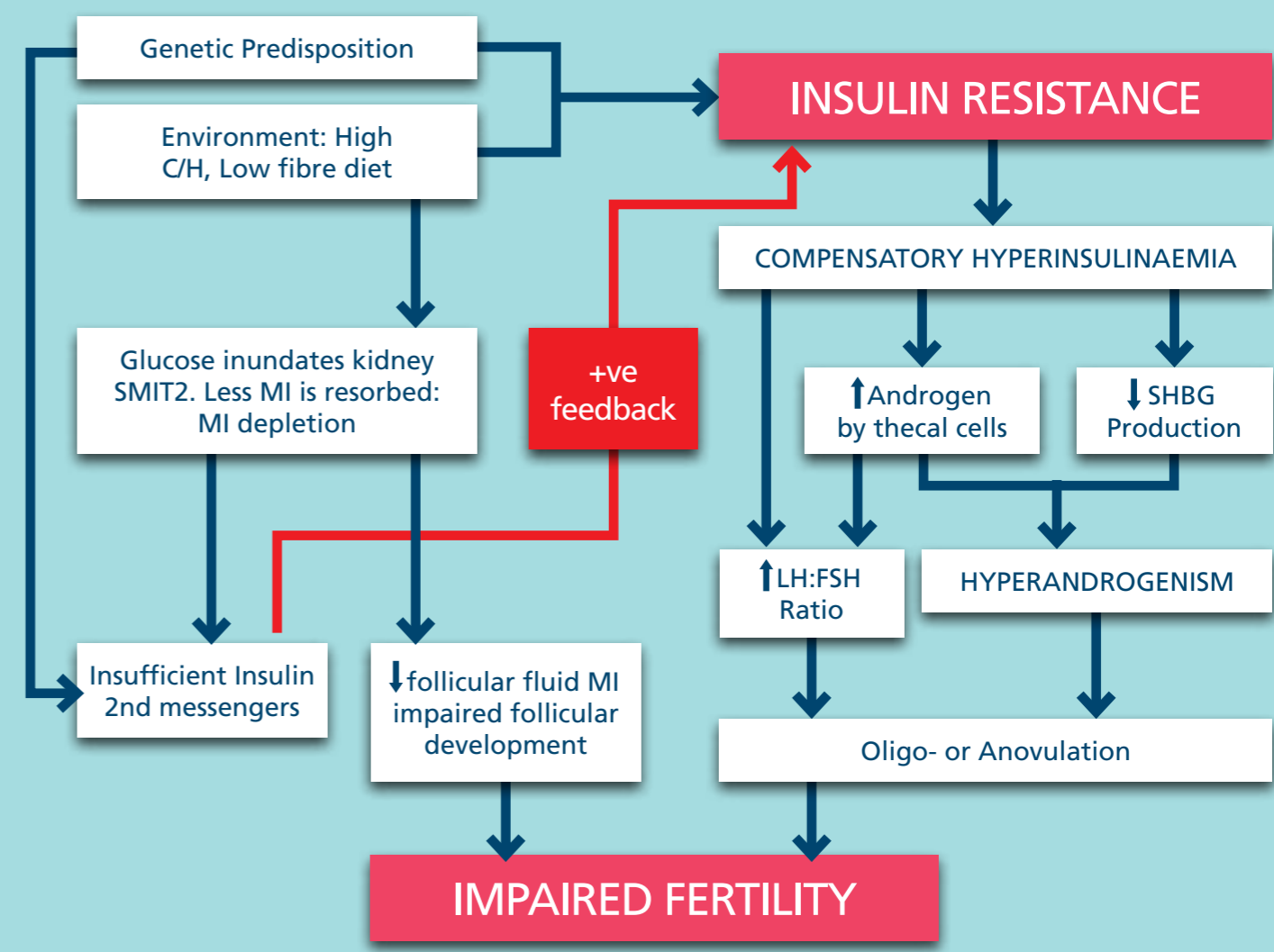
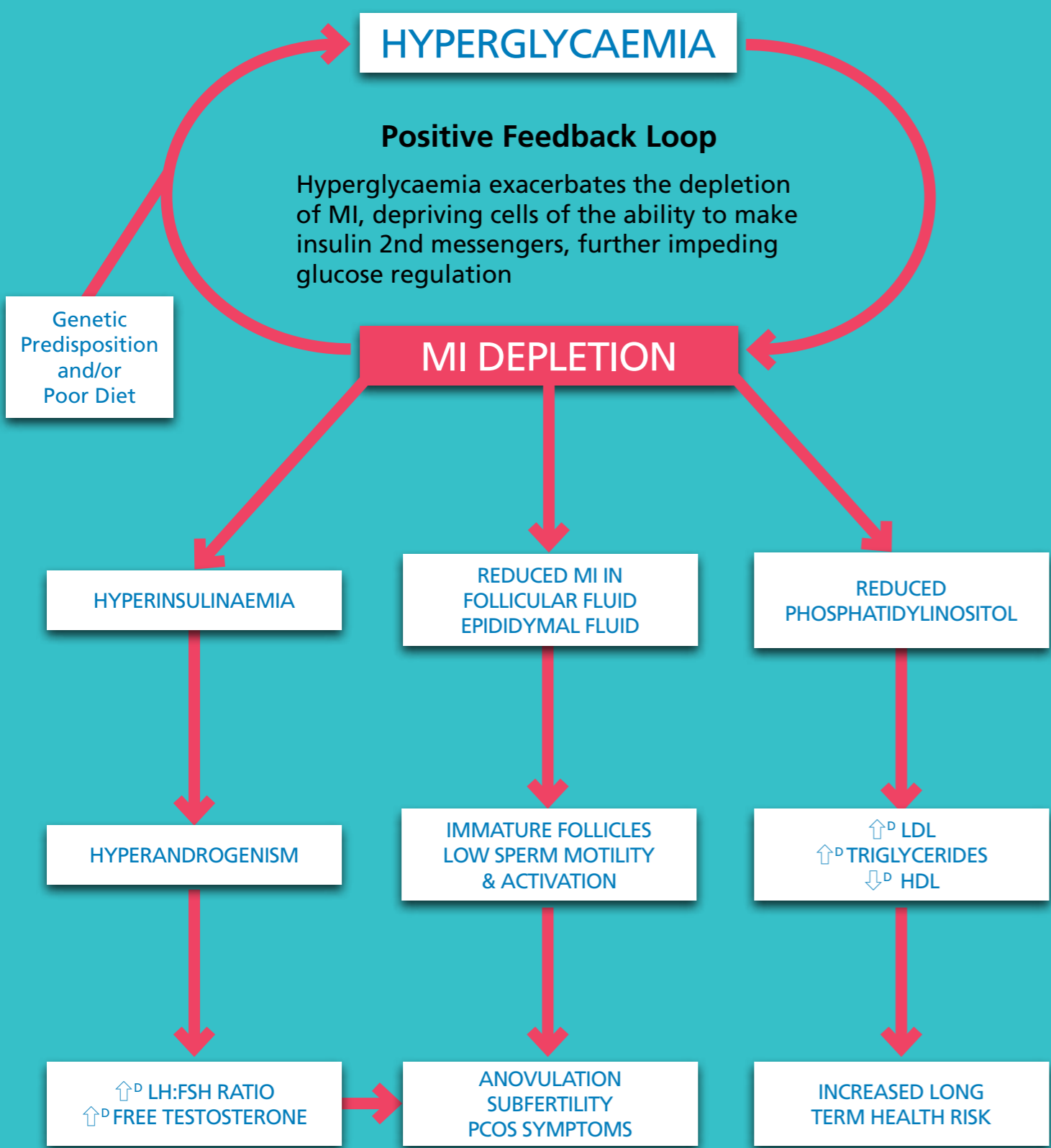
More myo-inositol is excreted as a result.

In T2D and PCOS, urinary myo-inositol is typically 4-6x & 2-3x higher than the normal state.^{6,7,8,9}

Positive Feedback Loop

Under hyperglycaemic conditions circulating myo-inositol is reduced. Myo-inositol is integral to at least 5 insulin second messengers so the resultant deficiency can lower insulin sensitivity. The reduced blood glucose lowering capacity increases the duration of hyperglycaemic conditions leading to still greater depletion of circulating myo-inositol.

Myo-inositol Depletion is associated with biochemical changes and impaired fertility

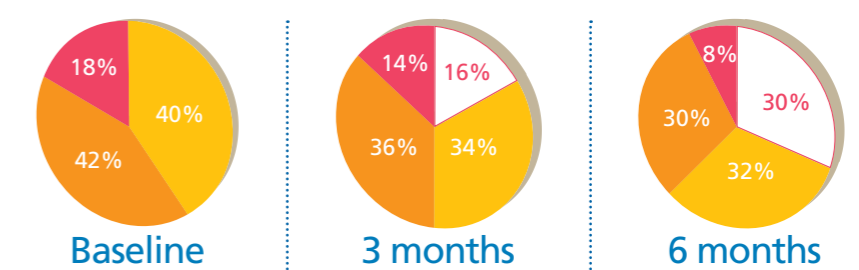


Biochemical correction of typical PCOS markers leads to clinical improvement¹⁵

N = 50	Baseline	+3 months	p
LH (mIU/ml)	14.1 ± 5.7	8.4 ± 2.2	0.005
Testosterone (ng/dl)	92 ± 38	64 ± 31	0.001
Free testosterone (ng/dl)	1.2 ± 0.2	0.7 ± 0.3	0.001
Basal insulin (µIU/ml)	12.2 ± 2.2	6.7 ± 1.1	0.005
HOMA Index	2.9 ± 0.8	1.4 ± 0.5	0.01

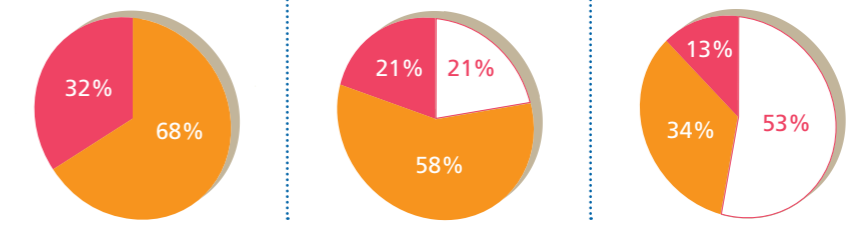
Hirsutism

- No hirsutism
- Mild
- Moderate
- Severe



Acne

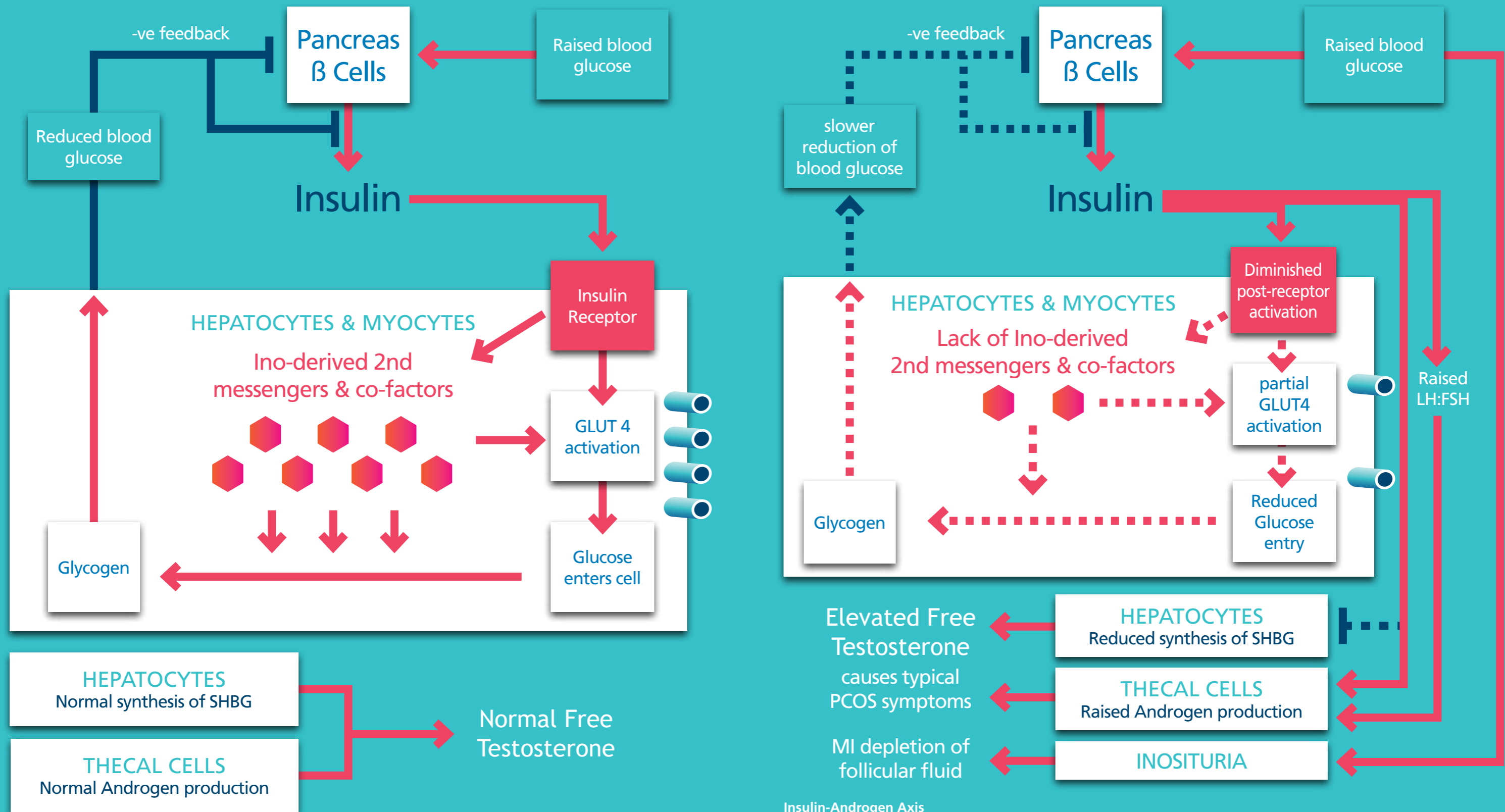
- No Acne
- Moderate
- Severe



Replenishing cellular and somatic myo-inositol can reverse the underlying depletion, break the positive feedback loop and prevent the biochemical and hormonal imbalances that are often associated with subfertility and PCOS, thereby returning the individual to within the normal reference ranges and restoring fertility.

Modified Ferriman Gallwey score @ baseline and 6 months.	11.4 ± 3.2	8.1 ± 2.6	p=0.003
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Where insulin resistance is associated with a metabolic deficiency, Replenitol can correct the problem at source



Insulin-Androgen Axis

At supraphysiological levels, insulin raises the LH:FSH ratio. The altered balance and hyperinsulinaemia stimulate the thecal cells to produce more androgens and block the production of sex hormone binding globulin (SHBG). Free testosterone rises as a result. Replenitol can correct the causative deficiency at source, uncoupling the insulin-androgen axis and improving signs and symptoms

Improved Bioavailability - Tablets vs Sachets

The proven effective dose for the treatment of PCOS and/or subfertility is 2g of myo-inositol taken twice daily. Replenitol tablets each contain 1g of myo-inositol so the recommended dosage is two tablets b.d. Alternatively, one tablet could be taken q.d.s. to further flatten the plasma concentration curve and increase bioavailability.

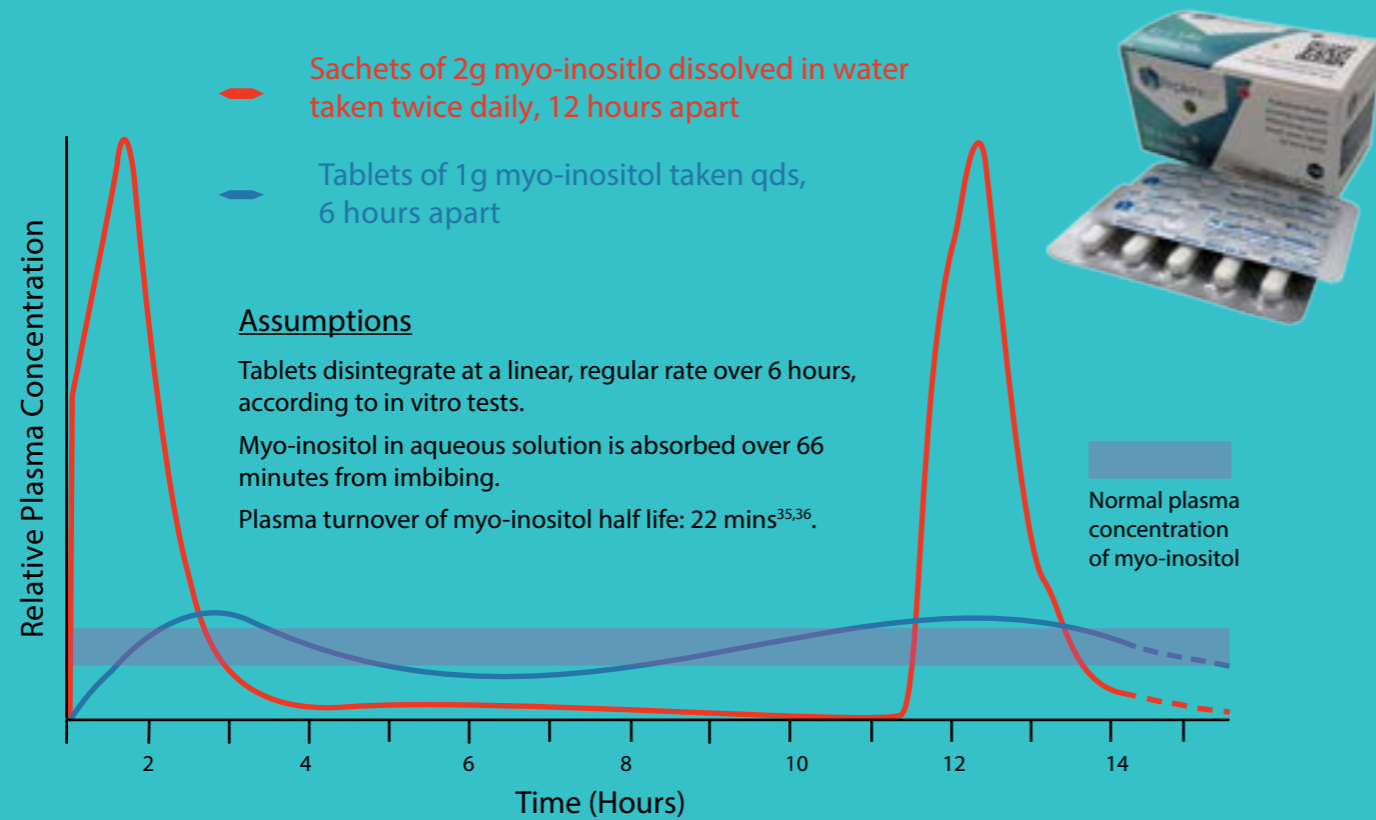
- Dietary myo-inositol is rapidly and almost completely (99.8%) absorbed in the gastrointestinal tract.
- Circulating fasting plasma myo-inositol concentration has been found to be approximately 30µM and it turns over with a half-life of 22 minutes^{35,36}
- A bolus dose would be almost (>97%) completely turned over in under 2 hours.
- Increasing the delivery window should provide greater bioavailability, lower upper plasma concentrations & more closely maintain the normal plasma myo-inositol concentration of 30µM for longer.

In combination with the OCP, Replenitol “offers a more effective long term therapeutic choice for controlling PCOS”¹⁶

Parameter	Group OC (n=75)		p: base v 12m	Group OCM (n=75)		p: base v 12m	OC v OCM 12m
	Baseline	12 months		Baseline	12 months		
Hirsutism (FG)	10.2±3.4	8.1±2.3	0.001	9.7±3.6	6.7±1.9	0.001	0.01
Testosterone (nmol/l)	2.34±0.26	1.65±0.19	<0.05	2.29±0.33	1.29±0.25	0.001	0.001
Androstenedione (nmol/l)	14.2±1.98	10.78±1.74	<0.05	13.95±1.02	8.74±1.33	<0.05	0.001
DHEAS (ng/l)	3167±543	2756±478	<0.05	3210±487	2538±506	0.01	0.01
LH (IU/l)	6.8±1.2	3.7±0.7	0.001	7.1±0.9	3.5±1.1	0.001	ns
HOMA-IR	2.7±0.8	2.5±0.9	ns	2.9±0.9	1.8±1.0	0.001	0.001
Total-C (mmol/l)	4.88±0.56	5.15±1.23	ns	4.67±0.23	4.84±0.89	ns	ns
HDL-C (mmol/l)	1.21±0.15	1.19±0.22	ns	1.28±0.43	1.45±0.71	ns	0.01
LDL-C (mmol/l)	2.92±0.44	3.05±0.67	ns	2.57±0.72	2.28±0.81	0.05	0.001



Comparison of plasma concentrations of identical doses of myo-inositol administered as a liquid and hardened tablet



The plot above is produced as an aid to demonstrate the difference between delivery of myo-inositol in liquid form (sachets) and tablets. It is not based on actual observations and makes basic assumptions of the underlying absorption and pharmacokinetic characteristics. It is for illustrative purposes only.

150 patients were randomised with half receiving just the OCP and the other half receiving the OCP plus MI 2g b.d for 12 months.

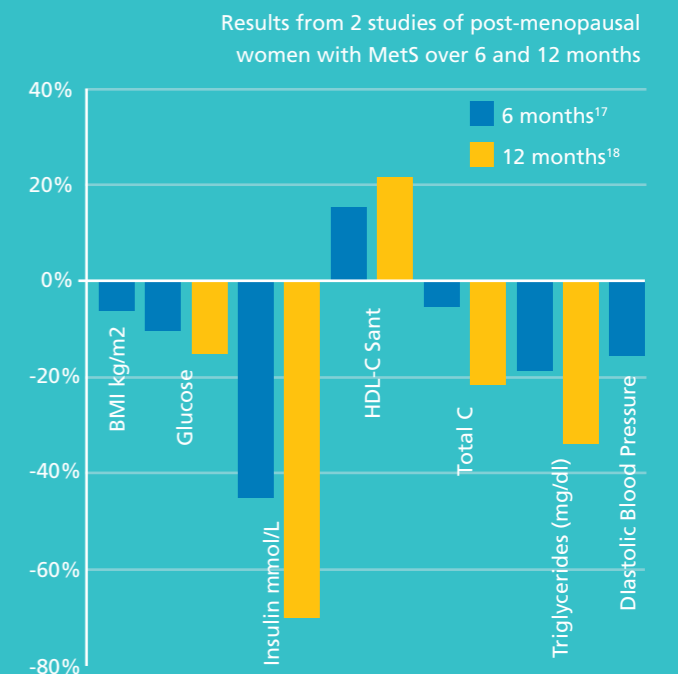
(HOMA > 2.0 insulin resistance possible; > 2.5 insulin resistance probable)

PCOS has long term health implications; Replenitol can reduce or eliminate the risk factors. It raises HDL and reduces LDL, BMI, insulin and diastolic BP^{17,18}

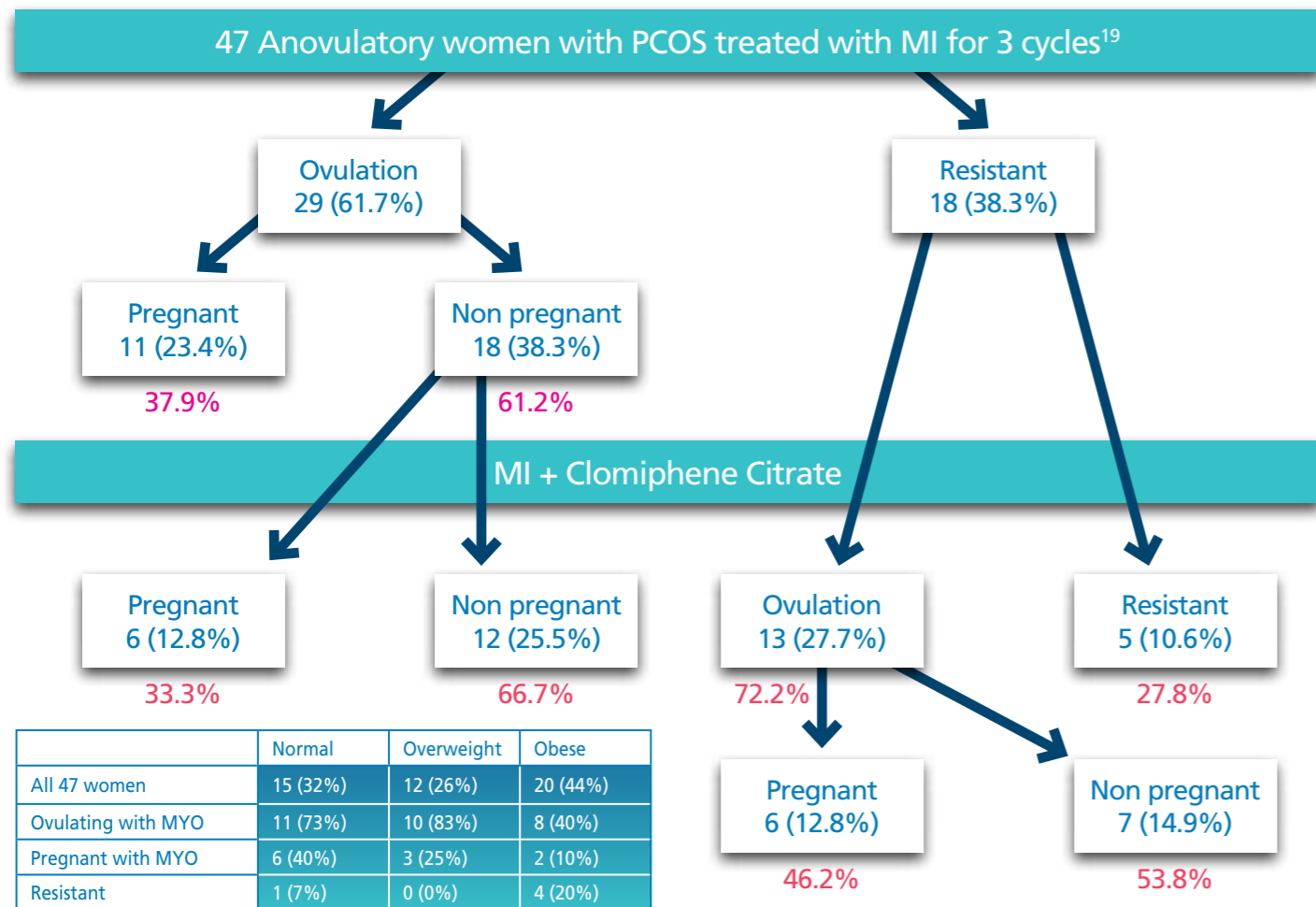
Correction of dyslipidaemia leads to reduction of long term risk factors^{17,18}

Metabolic Syndrome, PCOS and T2D share several signs, including impaired glucose tolerance and dyslipidaemia. Treatment with Replenitol can correct both, returning them to the normal range. The action on cholesterol is discriminatory, raising HDL-C and decreasing LDL-C by a similar amount.

6% reduction in BMI within 6 months¹⁷
 LDL reduced by over 20%¹⁸
 HDL raised by over 20%¹⁸



Boosts fertility alone or in combination with clomiphene



Increased top quality oocytes, pregnancy rate and live births²⁰

N = 149	Tx group	Control	p
Top quality oocytes	50%	30.8%	0.02
A grade embryos transferred	67.6%	55.7%	0.02
Clinical pregnancy rate	62.1%	42.9%	0.02

"overall quality of oocytes and, consequently, that of the embryos developed is significantly improved as a result of treatment with inositol and with them the number of clinical pregnancies obtained is increased"²⁰

"MYO supplementation is efficient in changing many of the hormonal disturbances of PCOS... it could modify the reproductive axis, improving oocytes quality and pregnancy rates."²¹

N = 50	Tx group	Control	p
Total rFSH dose (IU)	1839±520	2315±601	0.005
No of 75IU vials	27±6.5	31.8±9	0.002
No of cancelled cycles	1	4	0.005
No. of retrieved oocytes	6.5±3.1	10.8±8.8	<0.05
Top quality oocytes	82%	36%	<0.05
Clinical pregnancies	40%	16%	<0.05
Delivery rate	32%	12%	<0.05

Fertility boost for women without PCOS

Pretreatment reduces FSH dose by 12-19%, increases oocyte quality and shows a trend to increased pregnancy rates

Poor responders ²²	Tx	Control	p	n
Total rFSH dose (IU)	1975±298	2212±312	0.004	76
Ovarian Sensitivity Index	1.88±0.81	1.54±0.65	<0.05	
Oocytes of M2 classification	80.5%	66.6%	0.01	
Pregnancy rate	18.4%	15.7%	ns	

"myo-inositol seems to reduce gonadotropin dosage and the number of MII oocytes retrieved in non PCOS patients"²³

Multiple follicular stimulation for in women <40 years and FSH <10 mUI/m²³

	Tx	Control	p	n
Total rFSH dose (IU)	2084±648	2479±979	<0.05	100
Oocytes retrieved per patient	5.9±2.4	7.6±3.8	<0.01	
Embryos/patient	2.5±1.1	3.58±2.1	<0.001	
Patients receiving embryos	94%	94%	1	
Embryos transferred per patient	2.2±0.8	2.4±1	0.39	
Foetal hearts: implantation rate	18.70%	13.30%	0.08	

Comparison with metformin in women with PCOS²⁴

"n = 350 (intended) halted at 88"	Tx group	Control	p
Total rFSH dose (IU)	3900	2400	<0.001
Cancellation Rate	29.5%	13.6%	<0.05
M2 Oocytes	2.3	4	0.017
Clinical Pregnancy rate	29.5%	36.4%	ns

"In patients with PCOS and reduced ovarian reserve, metformin worsened the response to gonadotropins, and its administration should be stopped before the start of controlled ovarian hyperstimulation for IVF programs."

This study (designed to prove the effectiveness of metformin as an adjuvant in ovarian stimulation), was halted due to safety concerns for the women in the treatment arm.

51.2% more pregnancies & 58.5% fewer cancelled cycles among women with PCOS undergoing ART³⁷

A prospective, controlled, randomised trial among 196 sub-fertile women with PCOS assessed the benefits of myo-inositol as adjunctive treatment in ART outcomes. The results demonstrated positive biochemical changes leading to significant improvements in clinical outcomes.

Women presenting with insulin resistance showed a greater reduction in cancellation rate

PARAMETER	All Patients (n=176)			Subset with IR (n=92)		
	MI (86)	Control (90)	p	MI (47)	Control (45)	p
Treatment Arm (n)						
Spontaneous Pregnancies	9	0	N/A	Not included in this subset		
Administered FSH dose (IU)	689	777	0.02	656	773	0.02
Treatment Duration (days)	8.6	12.1	0.03	8.43	12.9	0.02
Clinical Pregnancies no. (%)	16 (18.6)	11 (12.3)	0.02	7 (14.9)	4 (8.9)	0.04
Cancelled Cycles no. (%)	3 (3.4)	8 (8.2)	0.06	2 (4.3)	5 (11.1)	0.04
Abortion Rate no. (%)	2/16 (12.5)	2/11 (18.2)	0.07	Not included in this subset		

Treatment Group Outcomes

- 9 Spontaneous Pregnancies prior to ART
- 15% reduction in total FSH dose
- Treatment Duration reduced by 3½ days
- 51% more Clinical Pregnancies
- 58.5% fewer Cancelled Cycles

Positive role in male fertility

In vitro use of myo-inositol on frozen and fresh semen samples has been shown to improve sperm motility, fertilisation rate and the percentage of Grade A embryos^{25,26,27}. It is also very well tolerated and begs the question of whether its use *in vivo* could replicate those benefits.

General population studies and studies of male relatives of women with PCOS have shown that a similar proportion of men share the altered biochemical profile typical of PCOS as women. MI depletion in men can give rise to insulin resistance and resultant hyperinsulinaemia which, in turn affects other hormones. It also impacts negatively on fertility rates as MI is normally highly concentrated in epididymal fluid.

Replenitol restores myo-inositol, reverses epididymal fluid deficiency and boosts fertility.

“MI is a safe supplement able to increase sperm parameters in patients with idiopathic infertility”²⁸

n=194	Treatment (n=98)		Placebo (n=96)		p: T v P at 3 months
	Before	3 months	Before	3 months	
LH (IU/l)	12.1±2.6	8.8±2.6	12.4±2.4	12.6±2.4	<0.05
FSH (IU/l)	16.7±4.1	10.7±4.1	16.7±4.1	16.8±4.2	<0.05
Inhibin (ng/l)	86±24	105±28	86±24	88±25	<0.05
Testosterone (nmol/l)	15.8±5.4	18.6±5.6	15.8±5.4	15.8±4.6	ns
Ejaculate volume (ml)	2.7±1.3	2.7±1.4	2.7±1.3	2.7±1.7	ns
Sperm concentration (million/ml)	20.2±4.6	26.4±4.4	20.2±4.6	20.8±4.3	<0.05
Total sperm count	46.6±12.6	57.6±14.4	46.6±12.6	47.8±11.2	<0.05
Progressive motility (%)	22.2±2.1	27.6±1.8	22.2±2.1	23.3±2.1	<0.05
Acrosome reacted spermatazoa (%)	34±8	41±11	34±8	36±10	<0.05

“Exogenous administration of MI significantly improves semen’s parameters both in patients with OA and in normal fertile men.”²⁷

Prevention of Gestational Diabetes

GDM is increasingly prevalent - seen in over 12% of pregnancies in Ireland²⁹ and 18% in the UK.³⁰ Effective preventative intervention with Replenitol can protect mother and baby from GDM complications throughout pregnancy and post-delivery.

Protects women with family history of T2D³¹

n=220	Ino group	Control	P value
Fasting Glucose (mg/dl)	77.0 ± 6.7	80.5 ± 8.0	0.001
1 Hour Glucose (mg/dl)	123.0 ± 30.6	133.0 ± 30.6	0.02
Birth Weight (g)	3,111 ± 447	3,273 ± 504	0.018
Macrosomia (>4000g)	0/99	7/98	0.007
Incidence of DM	6/99	15/98	0.04

A reduction in Risk of GDM of 65% was achieved by treating study participants with 2g of myo-inositol twice per day from the end of the 1st trimester

Prevents GDM in overweight women: BMI of 25-30³²

n=220	Ino Group	Control	P value
GDM Incidence	11.60%	27.40%	0.004



Treatment was associated with a 67% risk reduction of developing GDM"

Effective in many "at risk" groups

Also effective in obese women with BMI of >30³³

n=220	Ino Group	Control	P value
HOMA-IR reduction	-1.0±3.1	+0.1±1.8	0.048
Incidence of GDM	14.0%	33.6%	0.001

62% fewer cases in the treatment arm

"GDM risk seems to be reduced as a result of reduced insulin resistance"

An oral fasting glucose test during the first trimester can predict who is likely to develop GDM. Treating the at risk group with Replenitol could reduce incidence by 91.5%³⁴

n=75	Ino group	Control	P value
Abnormal OGTT	2/35 (6%)	27/38 (71%)	0.001
Required insulin therapy	1/35 (3%)	8/38 (21%)	0.053
Polyhydramnios	1/35 (3%)	7/38 (18%)	0.068
Neonatal Hypoglycaemia	0/35	10/38	0.038
BMI increase	2.3 ± 1.1	3.8 ± 2.4	0.001

Participants

Non-obese singleton pregnant women with an elevated fasting glucose in the first or early second trimester

Main outcome measure

Development of GDM on a 75g oral glucose tolerance test at 24–28 weeks' gestation. 71% of control group developed GDM, compared with just 6% in the treatment group.

GDM costs an estimated €3-5,000 per case

Leveraging these findings it may be possible to devise a targeted preventative strategy that can identify those at risk in early pregnancy and provide them with a safe, good value and highly effective treatment.



Two tablets, twice daily
for:

PCOS
Subfertility in women
Subfertility in men
Gestational diabetes
Dyslipidaemia

For more information please visit
www.replenitol.com

for a fuller, healthier life



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